University of Wisconsin-Madison ED/SBS IRB Application

Study # : 2016-1395

Principal Investigator: IGOR LUPYAN

#### **BASIC STUDY INFORMATION**

- 1.1 Indicate the appropriate IRB. NOTE:
  - If you are unsure which IRB to select, please refer to the guidance or contact an IRB office for assistance.
  - For studies that may qualify for review by the commercial (e.g., Western) IRB or NCI Central IRB, select the Health Sciences IRB below.

#### **⊙** Education and Social/Behavioral Science IRB

- C Health Sciences IRB
- O Minimal Risk IRB (Health Sciences)
- 1.2 Provide a short, lay-terms study title.
- \* How effective are different types of teams in solving different kinds of problems?
- 1.3 Provide the full, formal study title. NOTE: This is the title that will appear in correspondence.
- \* Investigating the role of inheritance in the problem solving abilities of teams
- 1.4 Is this study being transferred from another institution?
- \* OYes ONo
- 1.5 Identify the Principal Investigator.
- \* IGOR LUPYAN
- 1.6 Identify the points of contact for this study (limit of four).

#### NOTE:

- Points of contact can edit the application and will receive email notifications about this submission. For the HS and MR IRBs only, points of contact can also submit materials on behalf of the PI.
- $\circ$  If the PI is serving as a study point of contact, indicate that here.

\*

PIERCE EDMISTON
IGOR LUPYAN

#### PRINCIPAL INVESTIGATOR

Principal Investigator: IGOR LUPYAN

### 2.0 Does the PI (listed above) have a faculty appointment at UW-Madison?

\* OYes ONo

#### Madison VA (William S. Middleton VA Hospital)

- University policy requires that your study be reviewed by the Health Sciences IRBs if this study involves any of the following:
  - Any personnel holding an appointment at the Madison VA (William S. Middleton VA Hospital)
  - Any funding from the Madison VA (William S. Middleton VA Hospital)
  - Any Madison VA (William S. Middleton VA Hospital) sites or facilities
  - Other Madison VA (William S. Middleton VA Hospital) resources
- If your study involves any of the above, please return to the first page of this application, and select Health Sciences IRB or Minimal Risk IRB (Health Sciences).
- If you have any questions, please contact the HS-IRBs office at 263-2362.

#### **STUDY TEAM**

NOTE: All members of the study team (key personnel) must be listed on this page. Study team members can be listed as having either edit/email access or read-only access, but all study team members (apart from the PI and POC) must be listed in one category or the other.

If the study team includes anyone (including students) who is not affiliated with (e.g., employed by, holds an appointment at) the UW-Madison AND for whom you are requesting that UW-Madison serve as IRB of record, these individuals must be listed in either 3.1 or 3.2. If the study team includes anyone who is not affiliated with the UW-Madison for whom you are NOT requesting that UW-Madison serve as IRB of record, DO NOT list these individuals in either 3.1 or 3.2. The study protocol must include all external collaborators and their roles in this study.

**3.1 Identify study team members with edit/email access.** NOTE: Study team members listed here will be able to edit the application and receive email notifications regarding this study. Only the PI can formally submit materials to the IRB.

TALI DESPINS

**3.2 Identify study team members with read-only access.** NOTE: Study team members listed here will be able to read the application but will not be able to edit the application or receive email notifications.

ZOE HANSEN MARGARET PARKER JESSE REID HAILEY SCHIEDERMAYER YACONG WU

#### **STUDY TEAM: ROLES**

NOTE: Depending on the nature of the study or project, it is possible that some or all study team members will not fit into the categories below. If this is the case, select Not Applicable.

4.1 Identify the study team members who will be involved in identification and recruitment of subjects for this study, if applicable.

Person
TALI DESPINS
PIERCE EDMISTON
ZOE HANSEN
MARGARET PARKER
JESSE REID
HAILEY SCHIEDERMAYER
YACONG WU

□ Not applicable

4.2 Identify the study team members who will be responsible for obtaining informed consent, if applicable.

erson
ALI DESPINS
ERCE EDMISTON
DE HANSEN
ARGARET PARKER
SSE REID
AILEY SCHIEDERMAYER
ACONG WU

□Not applicable

# 4.3 Identify the study team members who will be intervening or interacting with subjects (e.g., administering surveys, conducting physical interventions), if applicable.

Person	
TALI DESPINS	
PIERCE EDMISTON	
ZOE HANSEN	
MARGARET PARKER	
JESSE REID	
HAILEY SCHIEDERMAYER	
YACONG WU	

□Not applicable

#### **FUNDING: GENERAL**

- 7.1 Identify the specific department or organization unit under which the research study will be conducted:
- \* PSYCHOLOGY-GEN (A487400)
- 7.2 Are you or do you plan on receiving funding to support this project (includes internal UW-Madison funds)?
- \* OYes ONo
  - 7.2.1 If the answer to 7.2 is Yes, will any of the funding be administered by the University of Wisconsin-Madison AND be at least one of the following types of accounts: 133 (not federally sponsored), 144 (federally sponsored), 233 (gift account), or 135 (WARF gift account). NOTE: For a 136 revenue account, please answer No to this question.

⊙Yes ○No

7.3 If there is no grant or contract funding this research, how will this research be funded?

#### **FUNDED STUDIES**

8.1 Identify all sources of funding for this study or project:

Other

8.1.1 If other, specify.

Startup funds to Gary Lupyan: 135 PRJ37LC

8.1.2 If 8.1 is fee-for-service, provide information about the funding sources.

Sponsor UDDS UW fund/account number Accounting Point of Contact There are no items to display

8.1.3 Does the study sponsor require in the study-specific contract or funding agreement, that this study follow ICH-GCP (International Council on Harmonization of Good Clinical Practice Guidelines)?

OYes ONo

#### FUNDING INFORMATION FOR STUDY CONDUCTED UNDER UW-MADISON

10.1 Provide information about each funding source administered by the UW-Madison that will support the activities of the study.

### Funding Source Information

	Funding Source Type	Award
	Fund	135
	MSN Number	MSN137859
	Project ID	PRJ37LC
	PI Name	LUPYAN, IGOR GARY
	Start Date	Wed Jul 1 00:00:00 CDT 2009
	End Date	Tue Jun 30 00:00:00 CDT 2020
	Sponsor	WISCONSIN ALUMNI RESEARCH FOUNDATION
	Primary Sponsor	No Value Entered
View	Title	New Staff
	Status	Active
	Federal	No
	Pending	No
	FA Rate	No Value Entered
	Department ID	487400
	Agency Reference Number	
	Budget	75000
	Grant Application	

#### **CONFLICT OF INTEREST (COI)**

- 13.1 Do ANY of the study team involved in the design or conduct of the research study, or their immediate family (spouse or dependent children), have a financial interest in an entity that (a) sponsors the study or (b) owns or licenses technology tested or evaluated in the study (including any agent, device, or software) that meets or exceeds one of the thresholds below:
- (a) Compensation of \$20,000 or more in a calendar year from a publicly traded or privately held business entity;
- (b) An ownership interest in a publicly traded business entity valued at \$20,000 or more or a 5% or greater equity interest;
- (c) Any ownership interest in a privately held business entity whatever the value;
- (d) A combination of compensation and ownership interest in a publicly traded business entity valued at \$20,000 or more;
- (e) A leadership position in a business entity (Leadership positions are positions with fiduciary responsibility, including senior managers (e.g., presidents, vice presidents, etc.) and members of boards of directors). Scientific advisory board membership is not a leadership position.
- \* OYes ONo
  - 13.1.1 If yes, identify the personnel who have this interest.

Person
There are no items to display

13.1.2 Upload the COI management plan(s).

File
There are no items to display

13.2 Do ANY of the study team involved in the design or conduct of the research study, or their immediate family (spouse or dependent children), have a proprietary interest in the research, such as royalties, patents, trademarks, copyright, or licensing agreement, that is relevant to this research study (including any agent, device, or software being evaluated as part of the research study)? NOTE: If this proprietary interest is managed through WARF, select Not Applicable.

Yes	⊙ No
Not	<b>Applicable</b>

13.2.1 If yes, identify the personnel who have this inte	rest.
--	-------

Person	
There are no items to display	

#### 13.2.2 Upload the COI management plan(s).

File	
There are no items to display	

## 13.3 Do ANY of the study team involved in the design or conduct of the research study have a financial interest that requires disclosure to the sponsor or funding source?

\* ○Yes **○No** 

#### 13.3.1 If yes, identify the personnel who have this interest.

Person	
There are no items to display	

#### **CONFLICT OF INTEREST (COI): CONTINUED**

- 14.1 In addition to the sponsor(s) of this study or project, are other companies or business entities involved or potentially affected in a significant way by this study or project?
- \* OYes ONo
  - 14.1.1 If yes, list those companies/business entities.
  - 14.1.2 If yes, describe the nature of each company/business entity's involvement.
- 14.2 Do ANY of the study team involved in the design or conduct of the study or project have any other financial interest that the investigator believes may interfere with his or her ability to protect subjects?
- \* OYes ONo
  - 14.2.1 If yes, identify the personnel who have this interest.

Person There are no items to display

- 14.3 Do any of the study team receive any incentives for recruiting human subjects or any other purpose directly related to the study or project?
- \* OYes No
  - 14.3.1 If yes, describe the nature of the incentive.

#### **CLINICALTRIALS.GOV REGISTRATION**

Registration at Clinicaltrials.gov may be required for International Committee of Medical Journal Editors (ICMJE) publication purposes as described below. Click on the help link above for additional information on these requirements.

**20.1 Does this study need to be registered at Clinicaltrials.gov to meet the ICMJE requirements?** Note: The ICMJE requires the registration of all health-related interventional studies investigating relationships between the health-related intervention and any health outcomes (interventions include: drugs, surgical procedures, devices, behavioral treatments, educational programs, dietary interventions, and process-of-care changes).

\* CYes • No

20.1.1 If yes, who has or will register the study prior to the enrollment of the first subject?

20.1.1.1 If other, specify.

#### TYPE OF APPLICATION

- 1.1 Indicate the type of application:
- \* Initial review application

#### STUDY LOCATION: GENERAL

- **1.1 Is this a multi-site study?** NOTE: A multi-site study involves at least one site or individual NOT affiliated with the UW-Madison. Select Yes if this study:
  - Will be conducted at sites outside the UW
  - Includes study team members NOT affliated with the UW
  - Involves sending or receving samples/data/images to/from collaborators outside the UW
- \* OYes ONo

NOTE: A lead site or coordinating center is typically responsible for coordinating activities at all other sites, receiving and analyzing data, and developing and updating the study protocol as needed.

- 1.2 Will UW-Madison personnel or personnel under UW-Madison IRB purview conduct research activities at sites outside of the US?
- \* ○Yes **○No** 
  - 1.2.1 If yes, specify.

There are no items to display

#### STUDY LOCATION(S): UW-MADISON SITES

- 3.1 Describe where the study will occur.
- \* The PI's lab (Brogden Hall Psychology Building).

#### **STUDY SUMMARY**

- 1.1 Will study activities involve interaction and/or communication with human subjects, even if only to obtain informed consent?
- \* OYes ONo
- 1.2 Provide the expected duration of the study (i.e., the time from IRB approval to completion of all study activities).
- \* 2 years.

#### **SPECIAL CONSIDERATIONS AND PROCEDURES**

2.1 If your study involves any of the following special procedures or considerations, additional information may be needed. Select all that apply. If none apply, check Not Applicable.

Interviews, focus groups, surveys, questionnaires, assessments (e.g., QOL, SCID, BDI, etc.)

#### RESEARCH DESIGN AND PROCEDURES

#### 1.1 What is the overall purpose of this project or study?

\* The purpose of this project is to better understand the role of inheritance in the problem solving abilities of individuals working together in teams. How is an individual's ability to generate a solution to a problem influenced by previous solutions to the problem created by the members of the team? How do individuals working on a solution to problem over time best utilize these existing solutions to leverage their own problem solving abilities beyond what could be accomplished by individuals working alone? The goal of this research is to test hypotheses about the role of social learning and solution inheritance in understanding human problem solving ability.

### 1.2 Briefly describe the procedures and interventions that will be performed for this project or study and all study arms involved.

\* Participants will be given a fixed amount of time to work on a solution to some problem. Specifically participants will play a computer game where they build tools out of basic resources, and use these tools to build other tools. In some conditions, participants will work alone. In other conditions, participants will be randomly assigned into teams. Some of these teams work together on the same problem at the same time. For participants in other types of teams, they will work one at a time, each inheriting the best solution (best tools) achieved by the previous teammate.

After working on a solution for the specified amount of time, participants will be asked to complete a questionnaire about their experience. They will be asked to rate their own abilities in solving the problem and also the perceived abilities of any team members.

#### **RISKS AND BENEFITS: GENERAL**

### 1.1 Describe any potential direct benefits to subjects. If there are no direct benefits, state this.

\* There are no direct benefits to participants in this study.

#### 1.2 Describe the potential benefits of this research to society.

\* This research has the potential to benefit society by identifying some of the ways in which individuals can work together more effectively in teams. Specifically, the goal of this research is to better understand the conditions under which inheritance of existing solutions is a more effective use of labor hours than starting over from scratch on a particular problem. The results of this work may influence managers and team leaders in business settings for how they organize labor.

#### 1.3 Does this study involve direct physical intervention with subjects?

NOTE: A physical intervention refers to study procedures that may pose a risk (however minimal) to a subject's body (e.g., blood draws, MRI scans, drug or device trials, exercise, dietary restrictions/supplements). Examples of activities that are NOT physical intervention include obtaining informed consent and administering surveys.

\* OYes ONo

#### RISK/BENEFIT ANALYSIS

## 4.1 Describe any potential psychosocial risks to subjects, such as psychological stress or confidentiality risks (including risk to reputation, economic risks, and legal risks).

\* Participation in this research involves playing a computer game, which involves extended amounts of time in front of a computer screen. The purpose of the game is to achieve a high score, which some may find stressful. In addition, participants will be working together in teams, which may also risk conflict among team members. There is also a risk for breach of confidentiality if team membership or participant identity is unintentionally revealed.

#### 4.2 Describe how ALL the risks of the study will be minimized.

\* To minimize the risk involved with extended time at a computer, participants will be made aware of the length of time of the experiment ahead of time and given breaks throughout the session. To minimize the risk involved with engaging in a competition, participants are informed they will be rewarded regardless of score. To minimize the risk of conflict among team members, team assignment occurs randomly and anonymously; the only way team members will interact is through the computer game interface, and not in person. Although members of the same team may be working in the same physical room, each will be assigned to a personal workstation and team assignment will not be made apparent. Similarly, the only interaction allowed between team members is sharing specific tools in the game, and free communication is not allowed.

### 4.4 Describe the provisions in place to identify and address unanticipated problems or complications.

\* Participants are encouraged to ask questions at any point during the research. All participants have the opportunity to submit feedback at the end of the experiment to inform the researchers of any problems that may have occurred over the course of the experiment. Participants are also informed how to contact the researchers directly with any questions they may have, and provided a contact for submitting problems or complications to an independent authority. We will work with the IRB to address any unanticipated problems or complications that arise from participation in the research.

#### SUBJECT POPULATION: GENERAL

- **1.1 Provide the total number of subjects required from all study locations.** NOTE: You must provide an integer. If you are enrolling a range of subjects (e.g., 50 to 100 subjects), enter the larger number.
- **\*** 500
- **1.2** Provide the number of subjects that will be recruited at sites under **UW-Madison purview.** NOTE: You must provide an integer. If you are enrolling a range of subjects (e.g., 50 to 100 subjects), enter the larger number.
- **\*** 500
- 1.3 Describe the main inclusion criteria.
- \* We will recruit broadly from the UW participant pool (http://uwmadison.sona-systems.com/).
- 1.4 Describe the main exclusion criteria.
- \* Persons under 18 years old will be excluded.
- 1.5 If any racial/ethnic group will be targeted for or excluded from this study, identify the group that will be targeted or excluded and provide justification for this. If this does not apply to your study, select Not Applicable.

Not Applicable

1.6 If men or women will be targeted for or excluded from this study, identify which sex will be targeted or excluded and provide justification for this. If this does not apply to your study, select Not Applicable.

Not Applicable

#### SUBJECT POPULATION: VULNERABLE GROUP CHECKLIST

2.1 If your study involves targeted enrollment of any of the following populations, additional information may be needed. Check all that apply. NOTE: If inclusion of any of these populations is only incidental, do not select that population. If none apply, check "None of the above."

None of the above

#### SUBJECT IDENTIFICATION AND RECRUITMENT: GENERAL

### 1.1 From what sources or by what methods will subjects be identified and/or recruited?

*		
Other		

#### 1.1.1 If other, specify.

We will recruit broadly from the UW participant pool (http://uwmadison.sona-systems.com/).

#### RECRUITMENT METHODS

**2.1 Describe the recruitment plan for this study.** NOTE: This description should address what methods will be used, when and how often they will be used, and how many times potential subjects will be contacted.

We will recruit from the UW participant pool (http://uwmadison.sona-systems.com/).

**2.2** If any advertisements will be posted, list locations and describe what advertisements will be posted at which locations. NOTE: Study teams must obtain permission from each location prior to posting recruitment materials.

Not Applicable

**2.3 Upload copies of recruitment flyers.** NOTE: Recruitment flyers are any advertisement that will be posted in public locations.

File
There are no items to display

Not Applicable

2.4 Upload copies of any other recruitment materials, including scripts, brochures, or advertisements (radio, newspaper, mailed letters, etc.).

File
There are no items to display

Not Applicable

- 2.5 Are you using an IRB approved recruitment database to disseminate recruitment materials or to contact subjects?
- \* ○Yes **○No** 
  - 2.5.1 If yes, provide the IRB protocol number of the recruitment database.
  - 2.5.2 Describe what will be disseminated to individuals who agreed to be included in the recruitment database.
  - 2.5.3 If the recruitment database is not the investigator's own, upload a letter of support for the use of the database.

File
There are no items to display

#### SUBJECT RECRUITMENT: CONTINUED

- 3.1 Will subjects be paid or offered other material inducements to participate in the study?
- \* •Yes •No
- 3.2 Will subjects undergo a preliminary screen to determine basic eligibility?
- \* OYes ONo

#### COMPENSATION

- 5.1 Is payment limited to covering travel expenses and other costs incurred by subjects as a result of study participation?
- \* OYes ONo
- 5.2 Describe any monetary compensation and explain how it will be paid to participants. NOTE: Include the amount of payment(s), proration, multiple payment schedules, etc.
- \* Not applicable.
- 5.3 If the subject is a child, describe what compensation will be given directly to the child and what will be given to the parent/guardian.

Not Applicable

5.4 Describe any compensation to be provided that is not monetary.

Participants will receive course credit in accord with the procedures set up by the Psychology participant pool (2 points / 1 hour in increments of 1/4 point).

□ Not Applicable

#### PRIVACY AND CONFIDENTIALITY

- 1.1 Describe the precautions that will be used to ensure subject *privacy* is protected (e.g., research intervention is conducted in a private room; collection of sensitive information about subjects is limited to the amount necessary to achieve the aims of the research).
- \* Although there may be other participants in the common lab space during consent and instructions, each participant completes the research in a private room containing only a single testing computer. Participants assigned to the team conditions are only allowed to interact anonymously through the computer interface. The computer interface does not allow for free conversation between team members. At no point before, during, or after the experiment will the participants who are assigned to team conditions be made aware of who their teammates were. Any participant ratings of other participants are collected confidentially and not shared with other participants.
- 1.2 Select how subjects are identified in the research records. Check all that apply:

Indirectly: Information identifying subjects is linked to data record but stored separately

- 1.3 Describe the measures that will be implemented by your research team to safeguard the identifiable subject information from unauthorized use or disclosure for both paper and electronic forms of information. Include how and where data will be stored.
- \* All data files will be identified only with a participant number and not the participants' names. The only records linking participants' names to participant numbers are physical consent forms, which will be kept in a locked file cabinet in the PI's lab space. Data files identified only by participant number will be stored in a secure MySQL database located within the PI's lab. Upon completion of the research, data will be further de-identified by removing all date and time information. This de-identified data will be shared publicly for other researchers to use. Participants are informed about this open data policy in the consent form.
- 1.4 Are you planning to retain data collected for this study for purposes not described in this application (e.g., future unrelated research project)?
- \* OYes ONo
  - 1.4.1 If yes, do you confirm that any future uses not described in this application will be submitted separately for IRB review?

○Yes ○No

#### PRIVACY AND CONFIDENTIALITY: CONTINUED

- 2.1 Will data be stored on laptops or portable devices?
- \* •Yes •No
  - 2.1.1 If yes, what additional safeguards have been put in place (e.g., link for coded data will be stored separately, data will be deidentified) to protect these data from risk of breach of confidentiality (e.g., theft of laptop, loss of portable device)? NOTE: Consult with your IT department about security of data storage on laptops or portable devices.

In all data files, participants are identified only by codes. No names are used. Data files will be stored on laptops for analysis, and will not be stored on laptops long-term.

**2.2** Will subject data, specimens, or images be shared outside the UW-Madison? NOTE: This is not referring to industry-sponsored clinical trials or cooperative group studies. For such studies, select Not Applicable.

○Yes **No**□Not Applicable

#### **INFORMED CONSENT: GENERAL**

1.1 What consent process or waivers of consent are you requesting for this study?

#### **INFORMED CONSENT: OVERVIEW**

#### 6.1 Describe when the consent process will occur.

\* Consent will be obtained immediately prior to participation.

#### 6.2 Describe where the consent process will occur.

\* In the PI's laboratory in Brogden Hall (Psychology). Participants will be consented by a research team member in private.

### 6.3 Do you confirm that all study personnel responsible for obtaining informed consent have the following qualifications:

- Are familiar with the details of the study;
- Will ensure subjects are provided with sufficient information to make an informed and voluntary decision about study participation;
- Are familiar with UW-Madison policies regarding informed consent.
- \* •Yes •No

### 6.4 Upload all consent documents and, if applicable, information sheets (e.g., consent form, assent form, translated consent documents).

- Please use the Upload Revision button (not the Add or Delete buttons) to upload revised consent documents. Using the Upload Revisions button will automatically replace the prior approved version of the documents being revised with the new version.
- Please remember to preview your consent documents and, if applicable, assent documents using the Preview Final Documents activity prior to submitting your application.

*	
File	
consent-form.doc	

#### **HIPAA: GENERAL**

NOTE: For guidance on the HIPAA privacy rule, including what constitutes individually identifiable information and Protected Health Information (PHI), refer to the HIPAA website. If the purpose of this study or project is to create a database or registry, contact the HIPAA Privacy Officer to determine whether it needs to be registered.

- 1.1 Will the research involve the access, collection, use, or disclosure of individually identifiable information and Protected Health Information (PHI)?
- \* ○Yes **⊙No** 
  - 1.1.1 If yes, are you or any member of the study team conducting the study under an appointment that is within the UW-Madison Health Care Component (HCC)? NOTE: The HCC of the UW-Madison currently includes SMPH clinical departments; School of Pharmacy (clinical units only); School of Nursing; University Health Services (non-student records only); State Laboratory of Hygiene; and Waisman Center (clinical units only).

CYes CNo

### INTERVIEWS, FOCUS GROUPS, SURVEYS, QUESTIONNAIRES, ASSESSMENTS

1.1 Describe the interview tools, questionnaires, or surveys that will be used. Click the add button to provide information about each tool to be used.

Fool Standardized	Computer task: Totems experiment No
Fool Standardized	·
Fool Standardized	·
	No
ile name	
ne name	Totems experiment
Tool Manner	In-person
Tool Manner Other	The Totems experiment is a computer task administered in the PI's
	lab space in Brogden Hall.
Date Modified	Wed Jan 11 11:51:15 CST 2017
Tool Description	Post experiment survey
Tool Standardized	No
File name	Post experiment survey
Tool Manner	Internet
Tool Manner Other	Post experiment surveys are conducted in an internet browser
	using a survey-building service like Qualtrics or Google Forms. No personally identifying information will be asked for in the survey.
Date Modified	Wed Jan 11 11:50:59 CST 2017
	cool Manner Cool Manner Other Cool Description Cool Standardized Cile name Cool Manner Cool Manner Cool Manner

## 1.2 Are any of the uploaded instruments used to assess cognitive or psychological status or function?

\* OYes ONo

### INTERVIEWS, FOCUS GROUPS, SURVEYS, QUESTIONNAIRES, ASSESSMENTS: CONTINUED

- 3.1 Is information that is potentially sensitive, stigmatizing, or psychologically disturbing (e.g., HIV status, illicit drug use, sexual abuse) being collected?
- \* OYes GNo
  - 3.1.1 If yes, justify why this information is necessary.
  - 3.1.2 If yes, describe how the risk of disclosure will be minimized, including addressing whether a Certificate of Confidentiality will be obtained.
    - 3.1.2.1 If you already obtained a Certificate of Confidentiality, upload it here.

File	
There are no items to display	

□ Not Applicable

- 3.1.3 If yes, describe any arrangements made to provide professional counseling or support resources to any subjects desiring such assistance as a result of their participation in the study.
- 3.2 If the study involves conducting focus groups, describe how the identity of individuals participating will be protected.

Not Applicable

3.3 If the study involves in-home visits, describe how mandatory reporting requirements (e.g., suspected child/elder abuse) will be met and how subjects will be informed of this reporting requirement.

■ Not Applicable

#### SUPPLEMENTAL INFORMATION

- 1.1 Does this submission represent a replacement of a protocol previously approved by a UW-Madison IRB (e.g., one closed under the campus Five Year Renewal Policy)?
- \* ○Yes **No**□Not applicable
  - 1.1.1 If yes, please provide the reason for the replacement (e.g., IRB required closure due to Five Year Renewal Policy):
  - 1.1.2 If yes, provide the previous number assigned to this protocol by the UW-Madison IRB that approved the study:
- 2.1 Provide any additional relevant documents (e.g., supplemental statistical justification information), if applicable.

File
There are no items to display

2.2 Describe what additional documents were added in 2.1.

#### **FINAL PAGE**

- 1.1 Do you certify that the information presented in this application is accurate?
- \* GYes CNo

To complete and submit this application to the IRB office, please follow the steps below:

- 1. Select Ready to Submit or Exit on this page to be directed to the application workspace.
- 2. In the application workspace, click the Submit activity to send the application to the IRB office. NOTE: The Submit activity is only available to certain study team members.

Tip: Select Hide/Show Errors at the top of this page to identify any omissions in the application before submitting it to the IRB office.