

The University of Arizona Consent to Participate in Research

Study Title: The explore-exploit dilemma in human decision making: behavioral and pupillometric, electroencephalographic, fMRI and TMS experiments

Principal Investigator: Robert Wilson

Sponsor: Robert Wilson, NIH

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

You may or may not benefit as a result of participating in this study. Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious, depending on the nature of the research.

1. Why is this study being done?

The purpose of this study is to learn how humans tradeoff information and reward when making decisions.

2. How many people will take part in this study?

About 8000 people. The number of participants in each experiment will vary from 20 to over 100.

3. What will happen if I take part in this study?

Before the study begins, you will be asked to complete a short questionnaire to assess your eligibility to participate in the study. The study may contain multiple parts, such that we may invite you to come back for the later parts on a different date.

For behavioral and pupillometric components of the experiment: you will be asked to perform a game on a computer. You will be seeing visual stimuli on the screen, and/or listening to audio stimuli, and you will be asked to make a response with a keyboard, mouse, and/or button box. We may also track your eyes using a special camera called a pupillometer. This uses infrared illumination to create reflections on the eyes that can be tracked with high accuracy, so that we can measure where you are looking and the size of your pupils. Infrared light can be found in our natural environment, for instance in candle lights. We may also record EOG signals, which measures your eye movements. Sensors will be placed on several spots on the skin of your face (specifically, forehead, above the eyebrow, and under the eye), gel will be placed in each disk in the sensor to be able to measure eye movements. We will take these recordings for 0.5 - 1 hour.

Video and/or audio recordings: During the task you may also have your vocal responses recorded using a microphone. We may also use a video camera to record you only when

you are performing the experiment, this is for the purpose of recording eye movements. You will be informed of when and for how long we will be recording you. All data will be stored on a server with no personal identifiers. Neither measurement entails no risk. We will take these recordings for 0.5 – 1 hour. We will ask for your signed consent to take these video and/or audio recordings on the last page of the consent form.

If you are participating in an EEG experiment: you will have a stretchy cap placed on your head to measure EEG signals. Gel will be placed in each disk in the cap to be able to measure electrical changes on the scalp due to brain activity. Once the EEG recordings are consistent, we will begin the experiment. We will have you perform a simple computer game while we record EEG. We may also track your eyes using a special camera called a pupillometer. This uses infrared light to measure where you are looking and the size of your pupils. This is completely non-invasive and carries no risk. After setup is complete you will perform a behavioral task on the computer and may, in addition, also answer some questions.

If you are participating in an fMRI experiment: the scanning session will be very similar to a routine clinical MRI scan of the brain. You will be asked to lie down on a table. Foam pads will be placed around your head to limit head movement during the study. The table will then be slid into the magnet. While in the scanner, you will be asked to lie still for approximately one hour, during which time several scans will take place. At times, you will be asked to perform the experiment task. In general, it will require you to observe stimuli presented on a screen. You will be asked to observe and/or respond to these stimuli by pressing a button. The scan will last approximately one to two hours, including about 30 to 60 minutes of preparation and about 90 minutes inside the scanner. Occasional breaks of 1 to 2 minutes will be provided, but during which you will remain in the scanner.

If you are participating in a TMS experiment: the trained TMS operator will first calibrate the TMS machine to establish an appropriate “dose” of stimulation. To do so, we will gently place the TMS coil on the surface of your head directly above the region of the brain that is responsible for hand motions. The TMS coil will then deliver single pulses that incrementally get stronger until a level is reached that causes your hand to twitch. The “strength of the dose” required to make your hand twitch is called the “motor threshold” and it varies for each individual. We will identify two separate motor thresholds; 1) Resting Motor Threshold (acquired at rest), and 2) Active Motor Threshold (acquired while participant gently pinches their thumb and pointer finger together). These “motor threshold” measures will then be used to calibrate the machine for the TMS protocols. Importantly, in addition to observing your hand visually, we will also attach sensors to the skin on your hand. These sensors will detect any activity in your muscles, which will yield a more accurate measurement for your personal “motor thresholds”.

During the TMS protocol, we will apply a combination of the following stimulation protocols: 1) 5 single TMS pulses, separated by 6 seconds, at 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, 100% and 110% of RMT; 2) stimulation at AMT for 2 seconds,

and rest for 8 seconds, repeated for a total of 10 times (i.e. 100 seconds with a total of 300 stimuli). Before and after the TMS protocol, you will perform the behavioral task.

4. How long will I be in the study?

If you are participating in only the behavioral and pupillometric experiment, the session takes about 60 minutes. If you are participating in either EEG or fMRI experiment, the session will last approximately one to two hours, including about 30 to 60 minutes of preparation and about 60 minutes for the experiment.

5. Can I stop being in the study?

Your participation is voluntary. You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The University of Arizona. If you are a student or employee at the University of Arizona, your decision will not affect your grades or employment status.

6. What risks, side effects or discomforts can I expect from being in the study?

If you are participating in the EEG experiment, or if we record EOG signal of your muscle movement: the only possible side effect we anticipate would be the very remote possibility of a mild skin reaction to the hypoallergenic ultrasound gel.

In some studies, we may also track your eyes using an eyetracker. This uses a special camera and infrared light to measure the location of your gaze and the size of your pupils. There are no known risks associated with eyetracking.

If you are participating in the fMRI experiment: the risks involved are minimal, and are limited to the risks present during routine MRI examinations. When near an MRI scanner, there is a potential for the powerful magnetic field to attract ferromagnetic metallic objects toward the magnet. For this reason, you will be carefully screened for previous exposure to metallic fragments or clips that may be inside your body. Similarly, you will be asked to place all metallic and magnetic objects in your possession (e.g. keys, credit cards) in a locker outside the magnet room.

While you are lying in the scanner, you will often hear beeping and knocking noises, some of which may be loud, that are produced by the scanning equipment. Disposable earplugs will be provided to diminish the noise.

You will always be able to communicate with the scanner operator throughout the study. Before and after individual scans, there will be breaks during which you will be able to talk with the operator through an intercom system. During a scan, the equipment noise will make it difficult to use this intercom, but you will also have at all times a signal ball that you can squeeze to let the operator know that you would like speak to them. If you

ever squeeze this, the operator will immediately stop the scan, and you will be able to use the intercom once again. If at any time you feel uncomfortable or unwilling to continue, no matter what the reason, you can request to immediately stop the study, and the operator will remove you from the scanner. Because you will not be physically restrained in the scanner, you could even pull yourself out if necessary; however, we ask that you instead use the intercom or squeeze bulb to tell us to remove you.

The bore of the magnet is a small space and some people may feel claustrophobic. Most participants rapidly grow accustomed to the space, but please let us know if you feel uncomfortable, and remember that you can always choose to leave the scanner at any time.

Although there is no known or anticipated risk to a fetus, you will not be allowed to participate in the study if there is any possibility you are pregnant. Beyond the risks described above, there are no known long-term physical risks associated with fMRI studies.

If in the course of this research scanning protocol we observe an anomaly in one or more of the MRI images, you will be informed of the observation. An anomaly does not necessarily indicate the presence of any disorder. Because our MRI scans are for research purposes only, they may be inadequate for the purpose of clinical diagnosis. Additionally, as researchers, we are not trained to clinically interpret MRI data. However, we feel it is important to inform you of any observations, as we cannot rule out the possibility that this anomaly may require medical advice. All information collected as part of this study will be made available to you for further examination by a medical professional. If you prefer not to be informed of anomalous findings, you must choose not to participate in the study.

If you are participating in a TMS study: Seizure is a theoretical risk with TMS. TMS procedures are associated with a very low risk of seizures. Out of over 10,000 people given various forms of TMS over the last two decades 16 people (~ 0.1%) have been reported to have had a seizure. Eight occurred before safety parameters were established in 1997. Of the other eight reports, six occurred either when the safe rTMS parameters were exceeded or other safety guidelines ignored, and the actual occurrence of a seizure has been questioned in the other two (i.e., convulsive syncope or pseudoseizure may have occurred). In a workshop convened by the National Institute for Neurological Disorders and Stroke (NINDS) in 1996, researchers in the field agreed upon a set of rTMS consensus safety guidelines, including recommended stimulation parameters and contraindications (Wasserman, 1998), and these consensus guidelines have been recently updated (Rossi et al., 2009). Widespread adherence to the 1996 guidelines has resulted in the virtual elimination of inadvertent seizures in rTMS studies (Rossi et al., 2009).

This study will only use levels of TMS that are within current safety guidelines, which have been formulated after careful review of thousands of participants/patients receiving TMS. Levels of TMS that fall within the safety guidelines have not been associated with seizure in appropriately screened individuals. No seizures have occurred in normal

volunteers with the dosage of TMS used in this study. To minimize this risk, you will be medically screened for any of the known characteristics that could lead to seizure. For example, persons with epilepsy cannot participate in this study. You will be visually monitored during the TMS for any signs of seizure or unexpected muscle twitching.

In spite of these precautions, there is a chance that you will experience a seizure. Should this occur, emergency facilities are available. If you have a seizure, you may require hospital admission and follow-up neurological evaluation. Having had a convulsion may make it difficult for you to obtain medical insurance, future employment, and to drive. It is not known whether having had one convulsion will make a person more prone to have future seizures. Should you have a seizure caused by TMS in this protocol, we will provide you with a letter documenting that the seizure was experimentally induced.

While only experienced by a minority of participants, the most commonly reported side effect of TMS is a "muscle-tension" type headache. If a headache occurs, it usually starts during or immediately after the TMS and lasts from minutes to hours after TMS. The headache usually goes away with standard over-the-counter pain medications (e.g., advil). Neck or scalp pain may also occur. You may also experience some discomfort on your head where the coil is held. This is due to contraction of scalp muscles. Numbness of the face lasting for a short time has also been reported in rare instances that may last for several weeks after receiving the procedure.

The click noises produced by the TMS procedure are loud enough to be damaging to your ears. You will therefore be required to wear earplugs, which will be provided by the experimenter to minimize this risk.

Additional side effects considered to be rare in TMS are dizziness, memory impairment, trouble concentrating, and acute mood changes. If these occur, these effects do not last long and should resolve without need for treatment.

There may be other risks that are currently unknown. There are no known long-term effects of TMS at this time.

There is also a risk of potential loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

Although we have tried to avoid risks, you may feel that some questions [or procedures] we ask you to do may be stressful or upsetting. If this occurs, you can stop participating immediately.

7. What benefits can I expect from being in the study?

You will not receive any benefit from taking part in this study.

205 **8. What other choices do I have if I do not take part in the study?**

206 It's your choice to or not to participate in the study, if you do not feel like continuing the
207 experiment, it's your right to leave at any point during the experiment. You may choose
208 not to participate without penalty or loss of benefits to which you are otherwise entitled.
209

210 **9. Will my study-related information be kept confidential?**

211
212 Efforts will be made to keep your study-related information confidential. However, there
213 may be circumstances where this information must be released. For example, personal
214 information regarding your participation in this study may be disclosed if required by state
215 law.
216

217 Also, your records may be reviewed by the following group (as applicable to the
218 research):

- 219 • The University of Arizona Institutional Review Board or Office of Responsible
- 220 Research Practices
- 221 • Other federal, state, or international regulatory agencies;
- 222 • The sponsor of the study, if any, may review the research records for monitoring
- 223 purposes.
224

225 Researchers will view your anonymous experimental data for coding and analytic
226 purposes, but they won't link the experimental data to your identity for any purposes.
227

228 To help us protect your privacy, we have obtained a Certificate of Confidentiality (CoC)
229 issued by the National Institutes of Health (NIH). The CoC is issued to protect the
230 investigators on this study from being forced to tell anyone about your participation in this
231 study, even under a subpoena. The information will be used by the sponsor, the
232 University, and regulatory agencies that support or oversee the research.

233 Even when a CoC is in place, you and your family members must continue to actively
234 protect your own privacy. If you voluntarily give your written consent for an insurer,
235 employer, or lawyer to receive information about your participation in the research, then
236 we may not use the CoC to withhold this information.

237 The Certificate of Confidentiality will not be used to prevent disclosure to state or local
238 authorities for reporting of child abuse or neglect, or as required by law to prevent harm to
239 self or others.
240

241 **10. What are the costs of taking part in this study?**

242 Aside from your time there are no costs to taking part in this study.
243

244 **11. Will I be paid for taking part in this study?**

245 If you are participating in partial fulfillment of the requirements for PSY150A or to earn
246 extra credit in another psychology class, you will receive experiment participation credit
247 at the rate of 1 credit per half hour of time. In some experiments, subjects receiving credit
248 may have an opportunity for receiving pay in addition to getting experimental credit. If
249 you are not participating in return for credit, you will be paid at a rate of \$10 per hour for

your participation in this experiment and a bonus of up to \$10 depending on your performance in the task.

12. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should seek treatment. The University of Arizona has no funds set aside for the payment of treatment expenses for this study.

13. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact the Principle Investigator, **Robert Wilson** at bob@email.arizona.edu.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Protection Program at 520-626-6721 or online at <http://rgw.arizona.edu/compliance/human-subjects-protection-program>.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **Robert Wilson** at 203-313-2962 bob@email.arizona.edu.

Signing the consent form

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

Printed name of subject

Signature of subject

Date and time

AM/PM

Investigator/Research Staff

I have explained the research to the participant or the participant's representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or to the participant's representative.

Printed name of person obtaining consent

Signature of person obtaining consent

Date and time

AM/PM

Consent for video or audio recordings

Video recordings

With your permission, we would also like to take video recordings during the task. Please sign below if you agree to be videotaped.

I hereby give my consent for video recording:

Printed name of subject

Signature of subject

Date and time

AM/PM

Audio recordings

With your permission, we would also like to take audio recordings during the task. Please sign below if you agree to be audiotaped.

I hereby give my consent for audio recording:

Printed name of subject

Signature of subject

Date and time

AM/PM

Investigator/Research Staff

I have explained the research to the participant or the participant's representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or to the participant's representative.

Printed name of person obtaining consent

Signature of person obtaining consent

Date and time

AM/PM