**Additional Elements of Consent**

**Instructions**

This resource document contains additional information that may need to be included in your consent form depending on the type of project. Should your consent form require this language, copy and paste the relevant header and content from this document into your consent form. This document provides some sample wording, however, as always, make sure that the content of your consent form is accurate to your project and IRB requirements.

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Additional elements of informed consent that IRB may require, if applicable

**Alternatives to participation**: [Explain other choices participants have if participants have any. If offering extra credit in a classroom setting for participating in research, you will need to state what other alternative to participating in the study is available - alternative must offer the same amount of extra credit and be equal to the amount of time the participant would spend on the research study.].

**New information that may affect your decision to participate**: We will inform you of any significant new findings that become available during the course of the study, such as changes in the risks or benefits resulting from participating in the research or new alternatives to participation that might change your mind about participating. [Discuss the procedures for informing/updating participants that may affect their decision to participate].

**Research related injury (required for projects that are greater than minimal risk)**: If you are injured or become sick as a result of this study, any emergency treatment will be at your cost.  UNM makes no commitment to provide free medical care or money for injuries to participants in this study.

It is important for you to tell the Principal Investigator immediately if you have been injured or become sick because of taking part in this study. If you have any questions about these issues, or believe that you have been treated carelessly in the study, please contact the Office of the IRB at (505) 277-2644 for more information.

*Note: If the above statement is not accurate for your project, see SOP 501 Informed Consent for what to include regarding research related injury.*

**Unforeseeable risks:** The particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or becomes pregnant) that are currently unforeseeable.

**Withdrawal:** Anticipated circumstances under which the participant’s participation may be terminated by the researcher without regard to the participant’s or the legally authorized representative’s consent;

The consequences of a participant’s decision to withdraw from the research and procedures for orderly termination of participation by the participant.

**Costs of participating:** Any additional costs to the participant that may result from participation in the research.

**Number of participants:** [Approved number of participants] people will take part in this study at the University of New Mexico. [Approved total number of participants across sites if this is a multisite study] will participate across the United States.

**Future use of biospecimens:** Your biospecimens (even if identifiers are removed) may be used for commercial profit and you [will or will not] share in any commercial profit.

**Return of research results:** A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to participants, and if so, under what conditions.

**Research involving biospecimens:** State whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

**Research conducted through MTurk:** State that the data provided by the participant may be collected and used by Amazon per its privacy agreement. Additionally, mTurk research is for residents of the United States over the age of 18; if they are not a resident of the United States and/or under the age of 18, they should not complete the survey.

Description of specific procedures

**Brain wave recording (EEG)**: An elastic cap with sensors attached to it will be placed on your head and the sensors will be filled with a gel. You will also have sensors attached around your nose and eye area. You will sit in front of a computer while pictures and words will be shown to you, or you will listen to sounds on headphones. You will be asked to make decisions about the information presented to you. The EEG takes about 1-2 hours.

**Transcranial Direct Current Stimulation (tDCS)**: tDCS is a low electrical current that slightly changes the way the brain works for a short period of time. tDCS applied to the head does this by giving a very weak electrical current through your scalp and into your brain. Electrodes will be placed on your scalp and upper arm using a special conductive gel. The electrodes are kept in place with a cap or sticky tape. The electrodes will give a very weak electrical current for 30 minutes, which may briefly result in a tingling and/or itching feeling at the electrode sites.

**Saliva Collection**: We will ask you for a saliva sample to collect genetic material (genes or DNA). We will provide you with a small cup and ask you to fill it with saliva up to a certain line (less than half a teaspoon). [For children studies, consider: "We get saliva from young children by touching the inside of the cheek with a sterile cotton swab."] We ask for your saliva to help us study (complete this sentence). Your saliva will be labeled only with a special number (code), which will remain linked to your identity (*OR IF DATA ARE ANONYMIZED*) which will de-linked from your name as soon as data collection is complete. We will store this sample until we are ready to analyze it. If you agree, we may keep your saliva for a very long time (indefinitely) for future research.

Description of risks related to specific procedures

**EEG:** There is a very small possibility that if you have sensitive skin (e.g., contact dermatitis) you may experience some skin irritation from the EEG gel or metal sensor. Throughout the sessions, assistants will be attending to you to keep you from becoming uncomfortable.

**tDCS**: We will be using a weak electrical current called tDCS to non-invasively stimulate your brain (or your arm). At the tDCS dose used in this project, no long-term harmful effects are known. tDCS has been safely administered to many people for the last several decades. Most individuals report only mild, transient tingling at the stimulation site. In a few cases, people have reported minor skin damage or irritation at the electrode site. In rare cases, the skin damage resembles a burn, much like sunburn, that may result in a scab or skin discoloration (resembling a suntan) at the electrode site that can last several days. If any of these are observed, we will postpone or terminate your participation in the project.

In addition to the tingling feeling at the start of tDCS, there may also be a warming sensation on the scalp. You will be encouraged to tell us about any pain or discomfort at the electrode sites throughout the tDCS procedure. If you tell us that the warming sensation becomes a burning sensation, the tDCS procedure will be stopped. If there are any signs of redness or irritation of the scalp, the tDCS will be stopped. There is the chance of receiving a small shock and a sensation of a short light flash if tDCS is stopped suddenly. To help keep this from happening we will ask you to keep as still as possible during the experiment. Also, if the electrodes are placed where they are uncomfortable in any way, please ask the research assistant to move the electrodes; do not try to do this by yourself.

**Genetic Testing**: The risks associated with genetic (DNA) tests are unknown. Genes may be shown at some point in the future to be related to disease, mental illnesses, or tendency to addiction. Since in some cases the results of these genetic tests may allow us to predict the risk of getting an illness, we will keep the results confidential (only scientists working on this research project will know the results). There may also be unexpected risks connected with this type of testing. At some time in the future, your genetic information could be used to identify you; however, we have put precautions in place to help reduce this risk. We will take every measure to protect you from the risks of other people finding out about the results of your genetic tests, which include people like insurance companies or future employers.

There are risks of loss of privacy, difficulty getting insured or being employed, and stigmatization (treated badly due to your genetic testing results). There are some protections afforded by the Genetic Information Nondiscrimination Act (GINA). For more information, please visit: <http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf>.

**Confidentiality of your information**: Specimens collected as part of the study will be labeled with your initials and a number; information (without your name) will be entered into a computer database/locked in a file cabinet in the Principal Investigator's office [or state other secured location]. [PI and researchers] will have access to your study information. Data will be stored for [# of years], and then will be destroyed.

For studies involving genetic testing of tissue samples, also explain who will be permitted access to the information and codes.

**If project has a Certificate of Confidentiality, include the following statement:**

To help us protect your information, this research study has a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, the research team cannot be forced to provide your name or any identifiable research data or specimens in any Federal, state or local proceedings unless you agree that we can share it. However, we still must report information to local authorities if we learn about child abuse or neglect, or intent to harm yourself or others.  Disclosure will also be necessary upon request from the Department of Health and Human Services (DHHS) or other federal agencies for audits or program evaluations (If not funded by DHHS, delete previous sentence.)

**HIPAA Authorization for Use and Disclosure of Your Protected Health Information**

As part of this study, we will be collecting health information about you and sharing it with others. This information is “protected” because it is identifiable or “linked” to you.

**Protected Health Information (PHI)**

By signing this Consent Document, you are allowing the following people to use your protected health information for the purposes of this study: [list all people that will access PHI or you can also create a document to give participants that lists these people]. This information may include: [list PHI, e.g. results of physical exams, medical history, body mass index, etc.]

In addition to researchers and staff at UNM and other groups listed in this form, there is a chance that your health information may be shared (re-disclosed) outside of the research study and no longer be protected by federal privacy laws. Examples of this include disclosures for law enforcement, judicial proceeding, health oversight activities and public health measures.

**Right to Withdraw Your Authorization**

Your authorization for the use and disclosure of your health information for this project shall not expire unless you cancel this authorization. Your health information will be used or disclosed as long as it is needed for this project. However, you may withdraw your authorization at any time provided you notify the UNM researchers in writing. To do this, please send a letter notifying them of your withdrawal to:

[PI Name]

[MSC]

1 University of New Mexico

Albuquerque New Mexico 87131

[PI Email address]

Please be aware that the research team will not be required to destroy or retrieve any of your health information that has already been used or shared before your withdrawal is received.

If you have questions about the privacy practices of the entity from which your PHI is being collected, you can request a Notice of Privacy Practices from your provider.

**Refusal to Sign**

If you choose not to sign this consent form and authorization for the use and disclosure of your PHI, you will not be allowed to take part in the research study.

**Clinical Trials:**

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

**European Union General Data Protection Regulation (GDPR):**

Your consent is voluntary and may be withdrawn at any time. At the time of withdrawal, your data will be deleted. Your personal data collected for this research will be deleted or anonymized by [period for which the data will be stored, or if undetermined, criteria for determining length of data storage]. Projected future use of your personal data includes [detail any future use].