***IMPORTANT: ALL SECTIONS ARE REQUIRED UNLESS OTHERWISE NOTED. BEFORE FINALIZING & UPLOADING THIS DOCUMENT: REMOVE: THIS SECTION, ALL [RED INSTRUCTIONAL TEXT] AND BLUE EXAMPLES.***

**CHAPMAN UNIVERSITY**

**CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT**

***[Title of Study]***

You are being asked to participate in a research study. Participation is completely voluntary. Please read the information below and ask questions about anything that you do not understand. A researcher listed below will be available to answer your questions.

If this form is being used to obtain parental permission for a child to participate in research, please change “You” to “Your child” throughout the document.

**RESEARCH TEAM**

**Lead Researcher**

Name and Title

Department

Telephone number and e-mail address

**Faculty Sponsor** *[If not applicable, please remove]*

Name and Title

Department

Telephone number and e-mail address

**Other Researchers** *[If not applicable, please remove]*

 *[List only those researchers qualified to be involved in the informed consent process]*

**STUDY LOCATION(S):**

**STUDY SPONSOR(S):** *[List all monetary and/or non-monetary support for this research. If none, state Chapman University, etc.]*

***Investigator Financial Conflict of Interest*** *[Required if there could be the appearance of a conflict of interest. If not applicable, please remove. If a study team member has a disclosable financial interest the Chapman University Financial Conflict of Interest Oversight Committee will develop specific language detailing the disclosable financial interest]*

*OR*

No one on the study team has a disclosable financial interest related to this research project.

**WHY IS THIS RESEARCH STUDY BEING DONE?**

The purpose of this research study is to *[Complete this sentence and tell the participant the purpose of the research. Be sure to explain the background of the research problem, and any experimental procedures being conducted] Examples: to explore attitudes of first-generation Americans regarding education by conducting a series of four surveys.*

**HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**

We expected \_\_\_\_\_\_\_\_ people will be in this research study. All study procedures will be done at *. . . [If different procedures will take place at different locations, specify accordingly]*.

**WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY AND HOW LONG WILL THEY TAKE?**

1. *[Explain the research procedures in chronological order. Include the expected duration of each interview or procedure. If the study involves multiple components (i.e., surveys, focus groups, observations, semi-structured interviews, accessing records, the collection of medical information or biological specimens), or multiple cohorts who will participate in different study procedures (i.e. parents, teachers, children, etc.) it is* ***strongly recommended*** *that you use headings or tables to delineate between different study components and cohorts****.***
2. *Participation in the study will include about [XX visits, interviews, etc.] and take a total of about [XX hours] over a period of [XX days/weeks].*

**AM I ELIGIBLE TO PARTICIPATE IN THIS STUDY?**

Please note this may not be a complete list of eligibility criteria. We have included a few examples of study criteria to help you better understand how your eligibility in the study will be determined; your study team will go through the study eligibility criteria with you to verify if you qualify for participation in this study.

*[List only the inclusion/exclusion requirements subjects would be easily able to identify, including age, gender, behavior (e.g., smoking) health status, disease status]*

***Inclusion Requirements***

You can participate in this study if you *[Complete this sentence using a bulleted list of inclusion criteria – use* ***lay******language****] Examples: are at least 18 years of age or older; live in Orange County; etc.*

***Exclusion Requirements***

You cannot participate in this study if you *[Complete this sentence using a bulleted list of exclusion criteria - use* ***lay******language****] Example: are taking high blood pressure medications.*

WHAT ARE THE POSSIBLE DISCOMFORTS OR RISKS RELATED TO THE STUDY?

*[For minimal risk studies]* There are no known harms or discomforts associated with this study beyond those encountered in normal daily life. The possible risks and/or discomforts associated with the procedures described in this study include: *[Categorize the risks by severity and include the likelihood of the risk/discomfort occurring. Make sure to consider all types of risks – psychological, social, economic, legal and physical]*

*Examples of risks/discomforts – [Keep all statements that apply to this study and remove/revise as applicable]: Examples: anxiety, embarrassment, social stigma (shame or disgrace); and invasion of privacy. Other statements:*

**Breach of Privacy and Confidentiality:** As with any study involving collection of data, there is the possibility of breach of confidentiality of data. Every precaution will be taken to secure participants’ personal information to ensure confidentiality.

*[For greater than minimal risk studies]* The possible risks and/or discomforts associated with the procedures described in this study include: *[Categorize the risks by likelihood and severity of the risk occurring. Make sure to consider all types of risks – psychological, social, economic, legal and physical.]*

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

***Participant Benefits***

*[If direct benefit to the subject is anticipated]* The possible benefits you may experience from the procedures described in this study include *[Complete this sentence – the description of subject benefits should be clear and not overstated] Examples: increase reading comprehension; improved writing skills; learning about ways to improve your memory*

*[If no direct benefit to the subject is anticipated]* You will not directly benefit from participation in this study.

***Benefits to Others or Society***

*[Insert a statement about possible benefits to science or society here] Examples: greater understanding of how grassroots organizations contribute to eco-awareness, greater understanding of how stress influences memory*

WHAT OTHER CHOICES ARE THERE IF I DO NOT TAKE PART IN THIS STUDY? *[If no alternatives, please remove this section]*

*[If subjects will be compensated with extra course credit*: *The course instructor offering extra course credit for participation in research must provide alternatives to earn extra course credit. The alternative assignment must require equal or less time and effort for the same amount of earned extra credit that you can earn through participation in research.]*

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

*[Keep all statements that apply to this study and remove/revise as applicable]*

***Compensation*** *[Keep all statements that apply to this study and remove/revise as applicable]*

*[If subjects will not be compensated]* You will not be compensated for your participation in this research study.

*[If subjects will be compensated through the social science lab]* You will receive extra course credit for an eligible course through the Social Sciences Subject pool. You will receive a ½ unit of course credit for each ½ hour of participation in this study. Total amount of credit you may earn is *[Enter total # of units]*.

*[If subjects will be compensated for one session]* You will receive *[Enter type of compensation and amount/value]* for your participation in this study. *Example: a $5 gift card to a local merchant, or: you will be entered into a raffle to win 1 of 10 Amazon gift cards worth $100; chances of winning are approximately 1 in 100.*

*[If subjects will be compensated for multiple sessions]* You will receive *[Enter type of compensation and amount/value]* for each [study component, such as a survey, experiment, or focus group] you complete. There are *[Enter # and type of study components]*. Total compensation for participation in this study is *[Enter total compensation for completion of the study]*. If you decide to withdraw from the study or are withdrawn by the research team, you will receive compensation for the visits that you have completed.

***Reimbursement***

*[If reimbursement will be provided]* You will be refunded for the following expenses that you incur *[Complete this sentence] Examples: parking fees, transportation fees*

*[If no reimbursement will be provided]* You will not be reimbursed for any out of pocket expenses, such as parking or transportation fees.

*Costs [Remove/revise this statement as applicable]*

You will be responsible for the following costs:

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

*[This statement is required for all Full Committee research studies].* ***Note: This statement cannot be altered.*** *If not applicable, please remove]*

It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study.  You can tell the researcher in person or call him/her at the number listed at the top of this form.

*[If study is unfunded, PI-initiated, or federally funded]*If you become ill or get injured as a result of this study you should seek medical treatment through your doctor or treatment center of choice. The University and/or researchers are not able to offer financial compensation nor to absorb the costs of medical treatment should you be injured as a result of participating in this research.

*[If study is industry sponsored]* If you have an injury or illness from participation in the study, or the procedures required for this study, the reasonable medical expenses required to treat such injury or illness may be paid for by the study sponsor. The coverage for such injury or illness is only available if the Chapman University Principal Investigator and study sponsor have decided that the injury/illness is directly related to the study drug, device, or procedures and is not the result of a pre-existing condition or the normal progression or your disease, or because you have not followed the directions of the study doctor. If your insurance is billed, you may be required to pay deductibles and co-payments that apply.

**WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?**

*[Required if subjects may be terminated by researcher and/or if there are adverse consequences (physical, social, psychological, economic, or legal) of the subject’s withdrawal from the study]*

You are free to withdraw from this study at any time. **If you decide to withdraw from this study you should notify the research team immediately**. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, or if your safety and welfare are at risk.

If you withdraw or are removed from the study, the researcher may ask you to *[Complete this sentence] Examples: return for a final visit or evaluation; if you are interested in continuing long-term follow-up procedures; complete an exit telephone interview.*

[When research is not subject to HIPAA regulations]:

If you elect to withdraw or are withdrawn from this research study, the researchers will discuss with you what they intend to do with your study data. Researchers may choose to analyze the study data already collected or they may choose to exclude your data from the analysis of study data and destroy it, as per your request.

**HOW WILL MY PERSONAL INFORMATION BE KEPT?**

***Subject Identifiable Data***

*[Explain whether subject identifiers will be linked to the research data]* *Examples – [Keep all statements that apply to this study and remove/revise as applicable]*

*[All/some]* identifiable information collected about you will be removed at the end of data collection.

*[All/some]* identifiable information collected about you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data. *[Explain why personal identifiers will be retained.]*

*[All/some]* identifiable information collected about you will be kept with the research data. *[Explain why personal identifiers will be retained.]*

***Data Storage***

*[Describe how the data will be maintained] Examples – [Keep all statements that apply to this study and remove/revise as applicable]*

Research data will be maintained in a secure location at Chapman University. Only authorized individuals will have access to it.

Research data will be stored electronically on a laptop computer in an encrypted file *[and* *is password protected].*

Research data will be stored electronically on a secure [*computer or network*] in an encrypted file *[with password protection].*

The *[audio/video recordings]* that can identify youwill also be stored in a secure location; then transcribed and erased as soon as possible.

The *[audio/video recordings]* will also be stored in a secure location; then transcribed and erased at the end of the study.

The *[audio/video recordings]* will also be stored in a secure location and transcribed. The recordings will be retained with the other research data.

***Data Retention***

*[Explain how long the research data will be maintained.] Examples –* *[Retain the longest option that applies and remove/revise as applicable]*:

The researchers intend to keep the research data until analysis of the information is completed.

The researchers intend to keep the research data until the research is published and/or presented.

The researchers intend to keep the research data for approximately \_\_ years.

The researchers intend to keep the research data indefinitely.

The researchers intend to keep the research data in a repository indefinitely. Other researchers may have access to the data for future research. Any data shared with other researchers, will not include your name or other personal identifying information.

The researchers intend to keep the research data for seven years after all children enrolled in the study reach the age of majority (age 18 in California).

**WHO WILL HAVE ACCESS TO MY STUDY DATA?**

The research team, authorized Chapman University personnel, the study sponsor *[If applicable; otherwise please remove]*, and regulatory entities such as the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare.

Any information derived from this research project that personally identifies you will not be voluntarily released or disclosed by these entities without your separate consent, except as specifically required by law. Study records provided to authorized, non-Chapman University entities will not contain identifiable information about you; nor will any publications and/or presentations without your separate consent.

While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy.

***Certificate of Confidentiality*** *[If not applicable, please remove]*

To help us protect your privacy, *[*we have obtained / are in the process of obtaining*]* a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet federal requirements.

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances. *[State here the conditions under which voluntary disclosure would be made (e.g., Examples: child abuse, elder abuse, domestic violence or sexual assault). If no voluntary disclosures will be made, the researchers should so state.]*

If applicable, discuss required reporting (include CU Mandated Reporter Statement).

All Chapman University employees are mandated reporters under California¹s Child Abuse and Neglect Reporting Act ("CANRA").  Whenever a Chapman University employee, in his/her professional capacity or within the scope of his/her employment, has knowledge of or observes a person under the age of 18 years whom the employee knows, or reasonably suspects, to have been the victim of child abuse or neglect, the employee must report the incident to the appropriate authorities.

**WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?**

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at [Insert contact information for the research team]

This research has been reviewed and approved by an Institutional Review Board (“IRB”). You may talk to them at 714-628-2833 or irb@chapman.edu if:

1. Your questions, concerns, or complaints are not being answered by the research team.
2. You cannot reach the research team.
3. You want to talk to someone besides the research team.
4. You have questions about your rights as a research participant.
5. You want to get information or provide input about this research.

**HOW DO I AGREE TO PARTICIPATE IN THIS STUDY?**

You should not sign this consent form until all of your questions about this study have been answered by a member of the research team listed at the top of this form. You will be given a copy of this signed and dated consent form to keep. **Participation in this study is voluntary.**  You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with Chapman University.

|  |  |
| --- | --- |
| AUDIO RECORDING: | **<If not applicable, delete this entire section>** |
| I have received an adequate description of the purpose and procedures for audio-recording sessions during the course of the proposed research. I give my consent to allow myself to be audio-recorded during participation in this study, and for those records to be reviewed by persons involved in the study, as well as for other professional purposes as described to me. |
|  | **\_\_\_\_­\_Yes**, I agree to allow the research team to **audio record** my interview(s). |
|  | **\_\_\_\_­\_No**, I do not wish to have my interview **audio recorded.** |
|  |  |
|  | Signature of Participant **<If applicable, include “(or Parent/Legal Guardian)”>** |  | Date |
|  |  |
| VIDEO RECORDING: | **<If not applicable, delete this entire section>** |
| I have received an adequate description of the purpose and procedures for video-recording sessions during the course of the proposed research. I give my consent to allow myself to be video-recorded during participation in this study, and for those records to be reviewed by persons involved in the study, as well as for other professional purposes as described to me. |
|  | **\_\_\_\_­\_Yes**, I agree to allow the research team to **video record** *(study procedures, my interview, etc.)* |
|  | **\_\_\_\_­\_No**, I do not wish to have my interview or procedure sessions(s) **video recorded.** |
|  |  |
|  | Signature of Participant **<If applicable, include “(or Parent/Legal Guardian)”>** |  | Date |

Your signature below indicates you have read the information in this consent form and have had a chance to ask any questions you have about this study.

***I agree to participate in the study.***

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 **Subject Signature Date**

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 **Printed Name of Subject**

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

***Legally Authorized Representative/Guardian Signature Date***

*­­­­­­­­­­­­­­­*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*­­­­­­­­­­­­­­­****Printed Name of Legally Authorized Representative/Guardian Relationship to Subject***

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

***Legally Authorized Representative/Guardian Signature Date***

*­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*­­­­­­­­­­­­­­­****Printed Name of Legally Authorized Representative/Guardian Relationship to Subject***

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 **Researcher Signature Date**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_

­­­­­­­­­­­­­­­ **Printed Name of Researcher**

**CHAPMAN UNIVERSITY**

**Experimental Subject's Bill of Rights**

**The rights listed below are the right of every individual asked to participate in a research study. You have the right:**

1. To be told about the nature and purpose of the study.
2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.
3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.
4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.
5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.
6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.
7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.
8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.
9. To receive a copy of the signed and dated written consent form and a copy of this form.
10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

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If you have any concerns or questions regarding the research study you should contact the research team listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the Chapman University IRB staff at 714-628-2833 or irb@chapman.edu.