|  |  |
| --- | --- |
| **The Claremont Colleges Services logo** | **Agreement To Participate in *Descriptive Project Title*** (IRB # \_\_\_\_\_) |

 [Please also insert your IRB ID# in the footer starting on p. 2. Your IRB ID# is assigned as soon as you create your protocol, before completing or submitting it.]

|  |
| --- |
| **Template Instructions**1. Text with a turquoise background serves one of two purposes. It is either part of the embedded instructions or part of an example. Please remove or replace all such text as you prepare your own form.
2. Replace the form title in header (p. 2 onward) with your ***Descriptive Project Title*** or a shortened version of it.
3. For all instructions, PI = Primary Investigator.
4. You may adjust the font size and font type to suit your audience.
5. **Present all elements of this form in *clear, simple, nontechnical* language.**
	1. **In addition, use language suited for the *age, reading level, and culture* of the subjects you invite**.
	2. A 2016 *Washington Post* article reported, “**50 percent of U.S. adults can’t read a book written at an eighth-grade level.[[1]](#endnote-1)**”
	3. **Some agencies and sponsors require** that consent forms use language no higher than **8th grade level**. Best practices suggest using **6th grade** level.
6. **DELETE** this instructions box when you are finished preparing the form.
 |

You are invited to [“volunteer for” or “be a subject in” or “take a survey for” or “be interviewed for”] a research project. [Volunteering may/will/will probably] not benefit you directly, but [Exceptions would be studies than include *interventions* intended to directly benefit subjects. In such cases, replace the first part of this sentence with a brief description of that benefit followed by “and”] you will be helping us [test/explore/develop \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_]. If you volunteer, you will [complete some activity or be asked\_\_\_\_]. This will take about [# of m/h/d/w…] of your time. Volunteering for this study involves no more risk than what a typical person experiences on a regular day [or “Volunteering for this study involves \_\_\_\_\_\_” filling in the blank with a description of the risk and its probability and seriousness]. Your involvement is entirely up to you. You may withdraw at any time for any reason. Please continue reading for more information about the study.

**Study Leadership:** This research project [or study] is led by [Include the name, title and affiliation of the TCCS Principal Investigator(s), **e.g.: “**Maria Kim, an Arts and Humanities Librarian at The Claremont Colleges Services”].

**Purpose:** [Provide a specific statement of purpose in nontechnical language, e.g., “The purpose of this study is to learn more about…” or “This study is designed to test the idea that…”. Summarize, in lay language, the scientific, scholarly, clinical, and any other objective(s) of the research. **E.g.,** The purpose… is to “…find out how people make financial decisions under different kinds of stress.” “…learn about the ways that health education influences people’s sexual attitudes and practices.”]

**Eligibility:** To be in this study, you must be… [State the specific inclusion/exclusion criteria, **e.g.,** “…a student in your senior year at Southern California College” “…in good health, not pregnant or at risk of pregnancy, and 18 years of age or older” “not have a heart condition” “…35-65 years old and a registered voter in Riverside County” …”a resident of the United States, and registered on Amazon’s mTurk”.]

**Participation:** During the study, you will be asked to… [Explain specifically, clearly, and in plain language appropriate to the age and education level of the participant pool, **what** subjects will be asked to do and **how long** it will take, **e.g.**: “…complete a questionnaire that will take about 20-30 minutes, asking about your education, work experience, job satisfaction, and family background.” “…come to a laboratory in Claremont for about two hours today, during which you will complete a questionnaire about your current health and your problem-solving style as a child and as an adult; participate in a computerized trading game; and let us draw about two teaspoons of blood from a vein in your arm; then come here again about two weeks from now to repeat most of these activities, which will take about an hour and a half.”]

[**If applicable:** For a survey or interview, one or more **examples of questions** should be included here, **especially** examples of any highly personal or sensitive questions. **If follow-up contact** is expected, be sure to fully describe the expected future contact and participation. If there is a structured **alternative** to participation, such as an alternate activity in a classroom setting or a way to gain comparable ‘extra credit’ with comparable effort, describe the alternative, **for example**: If you would rather not to be in this study, you may instead read a chapter/write a brief report on the subject of …]

**Risks Of Participation:** The risks that you run by taking part in this study are [minimal ***or*** moderate ***or*** substantial.] [Please do not vary from this terminology except to simplify for very young children; note that the IRB may ask you to revise the risk level you specify.] The risks include… [State in everyday language what those risks are, including any likelihood of physical harm or discomfort, psychological distress, unusual inconvenience, and/or disclosure of possibly damaging personally identified data. Say how the researchers will manage or control the risks. **If any deception will be employed** in conducting the study, include a warning here, e.g.: This description of the study’s risk level is accurate, but there is one detail about the study that has to be withhold until after you are finished with the questionnaire. We will explain fully at the end, so please do not skip the final page.]

**Benefits Of Participation:** [I **or** We] **do not** expect the study to benefit you personally. [If there are potential personal benefits, then remove “do not,” and please explain what the benefits are and indicate how probable/improbable they are. **E.g.**: This study “…might help you to control urges to smoke.” “…will provide you information that may help you select a major that is matched to your academic strengths.” **Do NOT** count any compensation you are offering as a benefit—compensation is covered separately below. **Please do NOT** include vague and uncertain subjectivities, such as “you should enjoy the experience,” or “you may learn something about yourself.”] This study will benefit the researcher(s) by… [Indicate how the researcher expects to personally benefit from the study, **e.g.**: “…helping me complete my graduate education.” “…enabling us/me to publish the results in a scientific journal.”] This study is also intended to benefit… [**If applicable**: Describe any likely benefits beyond the participant and researcher, i.e. benefits to a specific social group or institution if there is a reasonable and specific expectation of that; and/or to advance knowledge in a specific field of scholarship. Describe the possible social and/or scientific benefits using plain language, not jargon. Do not overstate the potential for impact that attaches to your study—the impact of any individual study is generally modest and is not guaranteed. The purpose of this section is to objectively inform, not to “sell” the study.].

**Compensation:** You [will/will not] be directly compensated [$ amount or description of item, if applicable] for participating in this study. [Describe any payment or other compensation, including the specific dollar amount(s), and when it will be provided. Also include any conditions associated with reimbursement, such as completing a certain proportion of the study. **E.g.:** “…a $10 Starbucks gift card at the end of the survey” “…$25 cash after completing the first session and $25 cash if you return and complete the second session.” “…a $1.25 credit on Amazon.com after finishing the survey.” “…$25 if you answer at least 75% of the questions.” “…a minimum of $50 and a maximum of $250 per day of participation, depending on the decisions made during the day, for a total of between $100 and $500. Most participants will receive between $200 and $250.”]

**Voluntary Participation:** Your participation in this study is completely voluntary. You may stop or withdraw from the study at any time [**If applicable, add**: or refuse to answer any particular question for any reason] without it being held against you. Your decision whether or not to participate will have no effect on your current or future connection with anyone at CGU. [**If applicable, add** the names of any other persons or organizations for which protection from negative consequences due to participation or nonparticipation is relevant and has been secured, **e.g.:** a referring clinician or counselor, a parent, a class, school, or place of employment where participants are recruited, etc.]

[**For group settings**, describe the alternative to participation. **E.g.:** If you choose not to fill out the survey, you may read or study at your desk**.**]

[**For studies involving children,** explain that a parent or guardian has given permission to participate, but the child can decide for herself whether she wants to be in the study or not, and no one will be upset or angry if she chooses not to.]

**Confidentiality:** Your individual privacy will be protected in all papers, books, talks, posts, or stories resulting from this study. [If confidentiality/privacy will not be promised, see “**If applicable’** below]. [**NEW REQUIRED statement when collecting identifiable data:]** We may share the data we collect with other researchers, but we will not reveal your identity with it **[OR**: “We will not use the data we collect for future research, nor share it with others.” The Revised Common Rule added a requirement to the basic elements of consent that the form ***must*** include a statement about whether or not data will be used for other research.**]**. In order to protect the confidentiality of your responses, [I **or** we] will… [Describe the **methods** you are using to protect your participants’ confidentiality/anonymity, such as securing data files, using random ID codes or pseudonyms, reporting only averages or other group statistics.

**NOTE: Anonymity ≠ Confidentiality. Anonymity** means that no identifying information such as email, street address, SSN or other official ID number, IP address, voice or image, or combination such as date of birth plus ZIP code, is being collected, so you will not know and it would be very difficult to infer or discover the identity of the person from whom any specific data were collected. **Confidentiality** means that you will know or can readily learn the participant’s identity, but you will not disclose or make it possible for anyone outside of the research team to learn it.]

[**If applicable:**, you must explain how any **audio/video recordings** will be used and what will happen to the recordings at the conclusion of the study. In general, **audio or video recordings are not anonymous**. You may erase such recordings when their research purposes are served (after transcribing, coding, or summarizing them), in order to protect participant privacy when that has been assured. If there is a specific reason to retain these recordings for a longer period, that reason and the period of preservation should be provided.

[**If applicable:** explain when and how participant **names or other identifying information will or may be used** in the final research document—in this case, make it very clear that participation is not anonymous or confidential.]

[**If applicable:** explain when and how you may share participants’ identity with other researchers who may recruit participation in other studies, including future follow-up studies. Explain whether/how one can participate in the study but opt out of identity-sharing for future studies.]

**Sponsorship** [***If applicable***]**:** This study is being paid for by…[Identify all Sponsoring Agencies that have provided funding (if any), by name and type of agency if that is not evident from the name, **for example**: the National Institutes of Health. …the US Air Force Research Laboratory. ….the California Endowment, a private not-for-profit foundation.]

**Further Information:** If you have any questions or would like additional information about this study, please contact [name of the PI or a representative of the research project, with phone number and email address]. As a member of The Claremont Colleges consortium, TCCS partners with the Claremont Graduate University for ethical and regulatory oversight of human subjects research and for other IRB services. The CGU Institutional Review Board (IRB) has approved this project. [**If status is EXEMPT**, replace “approved this project” with “certified this project as exempt**.” If applicable**, you may include information about other IRBs or ethical review boards in this paragraph.] If you have any ethical concerns about this project or about your rights as a human subject in research, you may contact the CGU IRB at (909) 607-9406 or at irb@cgu.edu. A copy of this form will be given to you if you wish to keep it. [**For online or telephone surveys**: You may print and keep a copy of this consent form. **OR** If you wish, I/we will be happy to send you a copy of this consent form.]

**Consent:** Your signature below means that you understand the information on this form, that someone has answered any and all questions you may have about this study, and you voluntarily agree to participate in it.

[**If applicable:** For online consent forms or other projects in which the IRB specifically waives the requirement for a participant **SIGNATURE**, a checkbox or equivalent signal rather than a signature block is appropriate and acceptable.]

Signature of Participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[**If Applicable:**] The undersigned researcher has reviewed the information in this consent form with the participant and answered any of his or her questions about the study.

Signature of Researcher \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_

Printed Name of Researcher \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Strauss, V. (2016) Hiding in plain sight: The adult literacy crisis. *The Washington Post.* [*https://www.washingtonpost.com/news/answer-sheet/wp/2016/11/01/hiding-in-plain-sight-the-adult-literacy-crisis/*](https://www.washingtonpost.com/news/answer-sheet/wp/2016/11/01/hiding-in-plain-sight-the-adult-literacy-crisis/) [↑](#endnote-ref-1)