**IRB Proposal for New Research Project**

***Please complete each of the questions listed below and submit the entire application, including all associated documents, ­in a single Word file or pdf.***

***NOTE: When completing checkbox items (e.g., Q9a, Q10a, Q17a), please avoid highlighting a response to indicate a response as this type of response sometimes does not appear clearly in printed copies of the proposal.***

**1. Project Title:**

**2. Principal Investigator(s):**

*Name:*

*Address:*

*Email:*

*Phone:*

 *Department:*

*NOTE: In the event of multiple principal investigators, please indicate which principal investigator should be the primary contact person for IRB inquiries.*

**2b. Research assistants and other key personnel (if any)**

*Name(s):*

**3. Are you a faculty member, student, or staff member? If you are a student, what is your expected year of graduation?**

**4. Ethics Training:** The IRB requires that the principal investigator(s), faculty sponsor, key personnel, and research assistants read the Belmont Report and complete a human participants research ethics training. Please check the IRB website for information on training courses that can be completed. At the end of the course, you, your faculty sponsor, and/or any research assistants will receive a “Completion Certificate” that should be included with your application. NOTE: If you plan to submit more than one proposal to the IRB, you can simply upload your completion certificate to your IRB Box account as a separate file and note on each proposal that you have submitted your certificate to your IRB Box account. Ethics training certificates must be submitted for all principal investigators, faculty sponsor, and research assistants. Because research assistants may be involved in multiple projects and to allow for easier updating of research assistants, we recommend that PIs create a folder within their IRB Box account for research assistant ethics training certificates. Then for this proposal and future proposals, simply note the names of appropriate personnel above and indicate where their ethics training certificates can be found if not directly included in this document.

**5. Are you using primarily qualitative or quantitative methods or mixed methods?**

**6. Does your project use federal funding?**

**6b. Does your project use any outside funding? If yes, please specify funding source.**

**7. Introduction to Project:**

In approximately 400 words, please 1) provide a brief review of existing bodies of relevant scholarship, 2) briefly describe your project (who your participants are, what you will be asking them to do, where you will conduct the study), 3) why you want to do this project (your scholarly motivation).

**8a. Research Questions under Investigation:**

Briefly describe the scholarly questions your study is designed to answer. What do you aim to find out? Please keep in mind that scholars should be clear and open regarding the purpose, methods, outcomes, and sponsors of their work. Scholars must also be prepared to acknowledge and disclose to participants and collaborators all tangible and intangible interests that have, or may reasonably be perceived to have, an impact on their work. (Adapted from the 2012 Statement on Ethics of the American Anthropological Association)

**8b. Scholarly Merit:**

Describe the scholarly merit of the project and any likely benefits of the project to our understanding of the situation or topic that you're studying.

**9a. Participants: Will your participants primarily include or target members any of the following protected or vulnerable populations? (please check all that apply)**

**☐ Patients ☐ Minors (under the age of 18)**

**☐ Non-English speaking participants ☐ Individuals with impaired decision making ability**

**☐ Prisoners or parolees ☐ Participants in other countries**

**☐ Economically or educationally ☐ Participants who may be unable to give**

 **disadvantaged participants informed consent legally**

**☐ Other** please specify:

**☐ None of the above**

**9b. Participants: Population of interest**

Describe the population of interest for your study. That is, whom would you like to study or understand? To whom would you like to generalize the conclusions of your project?

**9c. Participants: Selection of Participants**

Describe a) the group of people that you will be using as participants for your study (e.g., Claremont College students, adults in general, pre-school age children from a nearby pre-school, people from a particular community, etc.) and b) how your participants will be selected for participation in your study. Be sure to address considerations of equitable representation of gender and ethnicity whenever possible in keeping with the aims of your study.

**10a. Method: Does your project involve any of the following methods? (Please check all that apply.)**

**☐ Existing data bank or archives ☐ Film- , video-, Voice-recording of participants**

**☐ Interviews ☐Required responses**

**☐ Medical records ☐ The use of drugs or medication**

**☐ Taking physical specimens ☐ None of the above**

*NOTE: The “Required responses” item does not need to be checked if the only responses required relate to providing informed consent. If other responses will be required, please check the relevant box and then specify what responses will be required and why.*

**10b. Method: Description of what participants will do**

Describe exactly what participants will be asked to do in your project (beginning with the consent process, and ending with the debriefing process). Be sure to describe all tasks in sufficient detail so that the IRB will know exactly what participants will experience in your project.

**10c. Method: Study materials (e.g., interview questions, documents with images or text or descriptions of videos you will use in your work).**

Attach full text of all study materials to be used in your project.

**11a. Recruitment: How will participants be recruited?**

Describe exactly how participants will be recruited in your study (e.g., flyers, email recruitment, word of mouth, in person recruitment, visits to classes, online recruitment, etc.) and where the recruitment will occur.

**11b. Recruitment: Recruitment materials**

Include any recruitment materials you will use, such as email text, flyers, web announcements, Facebook event descriptions, verbal scripts, etc. Be sure to include exact text that will be used during the recruitment process.

**12. What will participants be told regarding 1) your role and the roles of any researchers on your project, 2) the research itself, and 3) what their participation in the research entails?**

**13a. Informed Consent: Do you plan to use written, oral, or electronic documentation of informed consent?** If you plan to use oral consent, please indicate why oral consent is merited in this case.Please note that generally written or electronic consent is required, unless to do so adds risk to participants or if it culturally inappropriate to do so (please see Question 21).

**☐ Written ☐ Electronic** (typically found in online research) **☐ Oral**

**13b. Informed Consent: Describe the procedures you will use to obtain informed consent.**

**13c. Informed Consent: Include full text for Informed Consent Document or Informed Consent Script.**

Begin your consent form with “a concise and focused presentation” of “**key information**” that enables a potential participant or legally authorized representative understand why one might or might not want to participate in the research.

 **Key elements** of an informed consent document or script include:

1) Introduction (This project is being conducted by Susie Student *as part of a senior thesis* at Scripps College);

2) Qualifications to participate (You are being asked to participate because you are 18

years or older, etc.);

3) Description of the general study purpose;

4) Amount of time it will take to participate;

5) Description of what participation involves;

6) Risks to participant;

7) Benefits to participant (including any payment that will be received);

8) Statement that participation is a) voluntary and b) can be stopped at any time without

penalty;

9) Description of what kind of data will be collected (anonymous, confidential, audio

recorded, written, etc.) and how that data will be stored and protected;

10) If collecting identifiable private information, provide information about whether or

not data “might be stripped of identifiers" and used for research studies or distributed to

another researcher for future research studies without additional informed consent from

the participant or their legal representative. NOTE: Please contact the IRB for more information if you plan for future use of identifiable data or biospecimens.

11) Please describe how results of the research may be disseminated or used (e.g., conference or other scholarly presentations, public presentations, shared with organizations studied, scholarly publications, uploaded to Scholarship@Claremont, shared online, etc).

12) If applicable, appropriate alternative procedures or courses of treatment that might be

advantageous to the potential participant.

13) Provide contact information for counseling in the case of emotional distress;

14) Provide contact information for investigators;

15) Provide contact information for Scripps IRB;

16) Invite participants to ask questions; and

17) Provide a way for participants to indicate their consent or lack thereof (signature line,

selecting a particular option button for online surveys, yes/no statement for oral consent)

And if applicable, consent forms must disclose whether:

1) Data may “be used for commercial profit, and whether or not the subject will share in

that profit”;

2) “clinically relevant research results will be returned” to participants and under what

conditions; and

3) “research will or might include whole genome sequencing”

NOTE: This information should be “organized and presented in a way that facilitates comprehension” for the average person, not just experts in your field. Please be sure to provide information that any “reasonable person” would want to know about the study and their participation in this study. Present information in “sufficient detail”, but do not “merely provide lists of isolated facts”.

NOTE 2: Under the revised Common Rule, an IRB may approve a proposal for an investigator to obtain information to screen, recruit, or determine eligibility of potential participants for a research study without informed consent, if 1) the information is obtained directly in oral or written form from the participant or the participant’s legally authorized representative, or 2) identifiable private information is obtained by accessing records to stored identifiable information.

**14. Does your project require any deception? If yes, please describe how participants will be deceived, why it is necessary for your project, why the data cannot be collected without use of deception (i.e., there is no alternative to use of deception), and how and when participants will be told about the deception.**

**15a. Data confidentiality, storage, and protection:**

Describe the kind of data you will collect (confidential, anonymous, identifiable), how you will protect the data, and how you will store the data. Note that if you will know the identity of any participants, even if you will not use their name in the final product, that is not “anonymous” data; it is “confidential” data. If the data are identifiable, please indicate whether participants have provided their consent for their data to be shared for purposes other than the original data collection.

**15b. Confidentiality: Describe the potential risks if confidentiality is breached.**

**15c. Is it possible that you might share the raw data with other researchers (directly or via an online database for sharing of study data)?**

If yes, please specify how you might share the data (e.g., open science database, shared with other researchers or collaborators for future studies, etc) and in what form the data might be shared (de-identified, identifiable, etc).

**16. Dissemination of results:**

Please specify how the results of the research may be disseminated (e.g., conference or other scholarly presentations, public presentations, shared with organizations studied, scholarly publications, uploaded to Scholarship@Claremont, shared online, etc) or used.

 *Students completing a senior thesis*: Seniors are required to upload their final written senior thesis to Scholarship@Claremont, unless you apply for an exemption with the college.

**17a. Sensitive Information: Will you be collecting any of the following information? (please check all that apply)**

**☐ Immigration Status ☐** **Illegal Behavior**

**☐ Sexual Behavior or Orientation ☐ Previous Crime Victimization**

**☐ Private mental or physical health information ☐ Other Sensitive Information**

**☐ None of the Above (please specify below)**

**17b. Sensitive Information: Describe the kind of information you want to obtain from participants and the level of personal sensitivity. If you selected “none of the above” for Question 16a, no response is needed here.**

**18a. Debriefing: Briefly describe your procedures for debriefing or conducting an exit interview.**

**18b. Debriefing: Include debriefing document or script for oral debriefing/exit interview.**

Elements of an exit interview/debriefing include:

1) thank the participants for their time and effort in the study;

2) remind the participants not to discuss the study or their experiences with others outside

of the Investigators and the IRB, since otherwise they could be affecting the responses of potential participants;

3) re-describe the purpose of the study;

4) review what the participants did, and if there is additional information to provide about

their participation, explain it (what manipulations they were exposed to, if any; more

specific descriptions of measures or questions, what deception occurred, if any; etc.);

5) provide full contact information for the Principal Investigator;

6) provide full contact information for the IRB;

7) provide contact information for follow-up counseling in the case of emotional distress.

If you are collecting identifiable data, please indicate that during debriefing you will give participants the opportunity to change their minds as to whether they wish their identifiable data to be used.

**19a. Risk to participants: Does your project involve greater than minimal risk to participants?**

*“Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.” (CFR 46.101)

**19b. Risk to participants: Assessment of risk to participants:**

Identify possible risks to participants, and describe how they will be handled.

**20. Compensation: Will participants receive payment for their participation?** If you plan to compensate participants, how much will you compensate them? Please also explain why you select this level of compensation.

**21. Benefits for participants: Direct Benefits for Participants**

Please describe any direct benefits to your participants, such as documented health benefits or other types of benefits

**22. Benefits of the Research Project:**

Please describe any benefits (beyond scholarly merit) for wider questions that address needs of specific communities or society at large.

**23. Will your research be conducted outside the United States?**

When research is conducted outside the United States, researchers must comply both with the U.S. regulations and with local policies and regulations governing the international research sites. The Office of Human Research Protections (OHRP) provides information on laws, guidance, and regulation in many different countries at <https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html> and <https://www.hhs.gov/ohrp/international/social-behavioral-research-standards/index.html>. Please consult these sites for more information on local requirements with regard to human participant research and be sure to follow the relevant laws, guidance, and regulations.

 Please describe what steps you will take to follow relevant laws or guidelines.

**23b. Cultural appropriateness and sensitivity:**

If you will be conducting your research outside the United States, it is important that you are respectful of the culture and/or country in which your research will be conducted. Please describe the cultural appropriateness of your project. Please be sure to describe any anticipated areas of cultural sensitivity in your research or research procedures and how you intend to deal with such sensitivities. For instance, in some countries, it would not be appropriate to provide contact information for local counseling services as such services may be unavailable or culturally inappropriate. Please also address any cultural barriers you might encounter and how you plan to approach these barriers. The IRB will consider alternative formats or methods for aspects of the research proposal typically expected, if such alternatives would be more culturally appropriate.

**24. By uploading this proposal to my IRB Box account, I, the principal investigator assure the IRB that all procedures carried out under the project will be conducted by persons legally and responsibly entitled to do so, and that any deviation from the submitted project (change in principal investigator, participant recruitment procedures, research methodology, etc.) will be submitted to the IRB for approval prior to implementation.**

In the case of multiple principal investigators, one investigator should upload the proposal to Box and other investigators should email the IRB at irb@scrippscollege.edu to signify that they have reviewed the proposal and agree to the above statement.

**24b. Faculty Sponsor**

Name:

Department:

Email:

All student projects must have a faculty sponsor. Please have your faculty sponsor either sign this proposal or email the IRB (IRB@scrippscollege.edu) to signify that they have reviewed and approved your proposal. In addition, please submit or have your faculty sponsor submit their certificate of completion for Human Participants Ethics Training (see Question 4), if they have not previously submitted this documentation.