Consent to be a Research Subject

Instructions: Delete all boxes (using the border feature) once you have customized each section. Boxes will contain the following:

Guidance and Suggestions
This text includes formatting requirements and helpful reminders.
Sample Statements
Sample statements can be edited for inclusion in your consent form. Text in brackets indicates fields that you should replace with your own information.

Text outside the boxes is formatting that does not need to change. **All language should be written at a 6th-grade reading level, free of jargon and written in concise lay language**.

If the consent form is more than 3 pages, you are required to include a summary of key information before the introduction (please refer to the consent template with key information).

Please leave a space 2 inches wide and 1 inch tall in the bottom right corner for the IRB stamp.

Title of the Research Study:
Principal Investigator:

Introduction

Guidance and Suggestions
Use the pronoun "you" throughout this document to refer to the research subject. Call yourself "the investigator." If this is student research, introduce yourself by name and affiliation, and add that you are conducting the research study under the supervision of your faculty advisor by name, title, and affiliation; this person is the faculty you list as the PI on the IRB application.
Sample Statements
This research study is being conducted by [include name and title of investigator(s)] at Brigham Young University [include the institutional affiliation of other investigators] to determine [purpose of study]. You were invited to participate because [state why they are invited to participate].

Procedures

Guidance and Suggestions
List all research activities for the research subject. Use bullet points to list multiple tasks. Be concise and clear. Adapt this to your own research.

Please state only those procedures that the research subject will undergo in chronological order. State where the research will take place, how long it will take, and when it will occur; if applicable, include the attire appropriate for physical activities. Include the information you would like to have if you were going to participate in this project as a research

subject. List the time each procedure will take and the total time commitment for the research subject, not the investigator.

Sample Statements

If you agree to participate in this research study, the following will occur:

- You will be interviewed for about [length of time] about [research topic]
- The interview will be audio-recorded to make sure the investigator remembers what you said correctly
- The interview will take place [insert location, i.e., in the investigator's office] at a time convenient for you, or it will take place at a time and location that works for you
- The investigator may contact you later to ask about your interview answers for approximately fifteen (15) minutes.
- You'll spend about [number of minutes] minutes in total

Risks/Discomforts

Guidance and Suggestions

List all reasonable risks of the study, which may include emotional discomfort, embarrassment, physical discomfort, pain, loss of classroom time, etc.

List specific ways you, the investigator, will minimize risks, including referrals to counseling services, treatment of an infection, licensed individuals to perform blood draws, etc.

For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs, and, if so, what they consist of, or where further information may be obtained.

Sample Statement

If applicable, add the following section with the heading **In Case of Research-Related Injury**. Note: **—This section should be included ONLY if the study presents physical harm.**

BYU makes no commitment to provide financial compensation, or free medical care should you be injured as a result of your participation in this research. Nonetheless, in the event of such an injury, after seeking appropriate medical attention, please contact [PI contact information].

Benefits

Guidance and Suggestions

The benefit comes as a direct result of the subject's participation in the research. The benefit should be fairly immediate, and the expectation of the benefit should be well-founded scientifically. If there are no direct benefits, please state that there are no direct benefits to research subjects. In a few limited cases, a subject may receive experimental therapy, etc., that are proven to provide direct benefits in a clinical trial. Extra credit and monetary inducements are not considered to be benefits.

Any indirect benefit to society (such as expanding scientific knowledge) can only be anticipated. There is no guarantee of benefit to society because you have not yet obtained results. If you talk about anticipated benefits, do so briefly and use the conditional tense, as in "Benefits may include..."

Sample Statement

There will be no direct benefits to you. It is hoped that your participation may help investigators learn about food storage practices that may be able to assist the Department of Homeland Security in improving their emergency preparedness education program.

Confidentiality

Guidance and Suggestions

Describe where and how each type of data will be stored and include the final disposition of the data, that is, what you will do with the data when the study is completed. Detail how the subjects' identity will be maintained. This includes the assignment of unique ID numbers to different data sources (questionnaires, class assignments, interviews, etc.), the questions of who will have access to subjects' identities, and the issues of maintaining subjects' anonymity in any publications or presentations that result from the research (e.g., by using pseudonyms or using only aggregated data). If data will be stored in cloud services, specify the service and how you plan to manage access to this data. For example, use of encryption, storing identifiable information separately from the rest of the research data, keeping only de-identified transcripts of interviews/focus groups in Box for analysis, etc.

Sample Statements

The research data will be kept [in a secure location/on password password-protected computer] and only the investigator will have access to the data. At the end of the study, all your information that could directly identify you will be deleted, and your responses will be kept [insert secure location].

Data Sharing

Guidance and Suggestions

This section may be combined with the confidentiality section, provided that all necessary information is included. Please note that certain U.S. states and international locations have specific personal data protection laws that must be followed. It is your responsibility not only to research and understand these laws but also to include appropriate language in the consent form to ensure compliance.

Sample Statements

We may share your data with other researchers or institutions to help with this study or related research. In most cases, we will remove your name and any direct identifiers before sharing — this means the data cannot easily be linked back to you.

[If the study data will contain information that directly identifies subjects.]

Your name and other information that can directly identify you will be stored securely and separately from the rest of the research information we collect from you. In these situations, only approved personnel will have access to the information that links the code to your identity, and strict data protection safeguards will be in place.

[For longitudinal research studies, include this statement.]

The investigators [plan to/may] contact you again as part of this research study.

Information that doesn't include names or personal details from this study might be shared with other investigators, with journals in which study results are published, and with research databases, etc. Before sharing the study data, we will remove or change any personal details that could directly identify you. Still, we can't promise that your identity will be completely anonymous.

[If you plan to share identifiable data for unspecified future research, include this paragraph, and omit the paragraph above.]

We would like to share information that could identify you with other investigators for future research studies. We will ask for your consent to do so at the end of this form. You can be in this current research study without agreeing to future research use of your identifiable information.

The results of this study could be shared in articles and presentations but will not include any information that identifies you unless you give permission for use of information that identifies you in articles and presentations.

Compensation

Guidance and Suggestions

If there is no compensation offered for the study participation, state: There is no compensation for participating in this study.
Explain the following, if any are relevant to your study:

- If payments will be prorated for any reason (including if a research subject withdraws before completing the study procedures).
- If there will be any type of bonus payment, or any payment amount is contingent on decisions/performance of the subject or a group of subjects.
- If you use a drawing (do not use the term "raffle" or "lottery"), explain the amount and total number of payments to be awarded; odds of winning (if known); approximate timing of the drawing; and how subjects who are awarded will be notified.
- If subjects will receive reimbursement for transportation, parking, or other expenses they incur due to participating in this study.
- If the study includes a student subject pool (like SONA), specify how much course credit study subjects will receive.
- If there could be costs to subjects for participating in the study (e.g., parking and transportation costs), describe those here.

Sample Statement

There is no payment or reimbursement for participating in this study.
OR
You will receive [type (e.g., cash, gift card, check) and total amount of compensation] for your participation in this study. [Insert additional explanation as outlined above]
OR
You will receive $10 for your participation; compensation will not be prorated.

OR
Research subjects will receive 5 extra credit points in ND&FS for completing the questionnaire. An additional 10 extra credit points will be given to focus group research subjects. For those who do not wish to participate in the research, 5 extra credit points can be earned by reading an article. An additional 10 points are available to those who wish to write a 2-page paper on the article.

Participation

Guidance and Suggestions
Provide a clear statement that the decision to participate is completely voluntary. Confirm that subjects can withdraw from the research study at any time.
Use wording appropriate for your study. For example, if you are administering a study to teachers in a public school, you may want to write "...you may refuse to participate entirely without affecting your employment or standing at the school."
Sample Statement
Participation in this research study is voluntary. You have the right to withdraw at any time or refuse to participate entirely, and it will not affect your class status, grade, or standing with the university.

Questions about the Research

Guidance and Suggestions
Provide information about who on the research personnel team the subjects can contact about the study.
For international studies, include the U.S. country calling code for the study team's contact phone numbers, and contact information for the local collaborator (if any).
Sample Statement
If you have questions, concerns, or complaints, you can contact the Principal Investigator [Name and contact phone or email] and [another investigator, such as a student if appropriate].

Questions about Your Rights as a Research Subject

Guidance and Suggestions
List the contact person of the IRB who is unaffiliated with the study and who advocates for the human subjects. In the U.S., it is BYU HRPP. For international research, the contact person should be someone in the local area with local contact information who would be able to inform research subjects of their rights. This person can be a project leader, organization director, or group facilitator. This should be a person who is not part of the research and who is able to communicate with subjects in their own native language.
Sample Statement [DO NOT ALTER]
If you have questions regarding your rights as a research subject, contact the Human Research Protection Program by phone at (801) 422-1461; or by email: BYU.HRPP@byu.edu.

Statement of Consent

Sample Statement
I have read, understood, and have been offered a copy of the above consent and desire of my own free will to participate in this study.

Name (Printed): _____ Signature_____ Date: _____