**Sample: *Social/Behavioral* *with Biomedical (MRI, blood draw, saliva sample, etc.) Component* Consent Form**

Tips to writing a consent form:

* Always write the consent form in the 2nd person (i.e., “you are” or “your child will” for parental consent). Refrain from using 3rd person terminology (i.e., “they are”) and terms such as “participants are”. Instruction should be targeted towards an individual.
* Language should be clear, concise, and understandable to the subject population. Typically for adult subjects, consent forms should be written at an 8th grade reading level.
* Avoid the use of exculpatory language, such as “guarantee confidentiality”
* Statements *in blue brackets and italics* indicate instruction or examples. Statements in black indicate sample language that can be used. All sections can be modified according to the specific protocol procedures.

**CONSENT TO PARTICIPATE IN RESEARCH**

[*Title of Study*]

[*Lead Researcher/Principal Investigator*]

Name, Title, Department

Telephone and email address

[*Other Researchers/Collaborators*]

*List only those researchers involved in the human subjects research*

[*Study Sponsor(s) if applicable*]

*If the Study Sponsor is the Department of Defense, include required DOD language where applicable in consent*

[*NOTE: The Summary of Key Information is intended to help participants understand* ***complex procedures, multiple sessions/tasks****, or the most important foreseeable risks (e.g., discomforts, time commitment). Use a bulleted list to describe the procedures, time commitment, and risks/discomforts. If this does not apply to your project, delete this section.]*

**Summary of Key Information:**

You are being asked to participate in a research study. Below is some key information that will help you decide if you want to participate. Please read the information below and ask any questions about anything you do not understand.

* This study is about [*state the study topic in non-technical terms*]
* If you participate, you will be asked to [*briefly explain all procedures the participant will be expected to complete and their expected duration*]
* Your overall expected time commitment will be [*state the total time commitment*]
* [*State any particular reasons that a person would want to volunteer for this research. This could include compensation or a chance to contribute to science.*]
* [*State the most significant reasons why a participant might not want to participate in the research. These could be risks posed by the research or any inconveniences that participants might experience.]*

**Purpose:**

You are being asked to participate in a research study. The purpose of the study is to… [*State what the study is designed to discover. Avoid technical language. Be succinct - 2-4 sentences usually suffice*.] [*If appropriate*]: Approximately [*state total accrual goal for number of subjects*] individuals will take part in this study.

**Procedures:**

If you decide to participate, we will ask you to...

[*Describe in simple language exactly what the participant will be expected to do in chronological order. The following information should be included, if applicable:*

* *The location of where the research activities will occur,*
* *A description of the research interactions, interventions, and data collection procedures (survey, interviews, focus-groups, observation, physical interventions, physiological interventions, etc.). Include if any procedures are experimental and if any procedure involves audio-visual recording*
* *The number, duration, and frequency of any procedures and overall expected time commitment. If this is a longitudinal study state, “*You will be contacted again as part of this project.” *Include the time interval for contacting participants.*

[*Note: If the procedures involve collecting sensitive information or questions that might be disturbing or upsetting, include some examples or describe the sensitive topic involved.*]

[*Note:* *If there are screening procedures inclusion/exclusion criteria, list and describe screening tests/procedures, inclusion/exclusion criteria as appropriate.*]

[*Note:* *If the study involves collecting biospecimens, such as saliva, blood, or other biological materials, state the collection method (e.g., self-finger prick) and what information (genetic, hormone levels, etc.) will be analyzed and why. State whether the research will (if known) or might include whole genome sequencing.*]

**Risks:**

The possible risks and/or discomforts associated with the procedures include: [*Describe the risks, discomforts and/or inconveniences from the research that the subject may reasonably expect. Risks may include (1) psychological risks or social risks, (2) physical risks, (3) confidentiality/privacy risks, (4) data storage risks, (5) risks to autonomy or coercion of subjects, and (6) other risks. Any risks identified on the RISKS TAB of the ORAHS protocol must be included in the consent forms/information sheets*.]

We will try to minimize these risks by: [*State what you will do to mitigate risks to participants*.]

[*If there are no risks, then state* “There are no anticipated risks to participating in this project.”]

***NIH Funded Studies:***

[*If the study is* ***funded by NIH****,* *include any risks, for storing and sharing of identifiable data (e.g., re-identification, etc.) associated with broad sharing of the data*]: Possible risks associated with sharing information in a publicly-accessible repository include:

**Benefits:**

[*Provide a brief description of benefits, if any. If there are no direct benefits, then state* “There are no direct benefits to participating in this project.” *Note: payment is not considered a benefit.]*

**Confidentiality:**

*[State how confidentiality will be protected and privacy will be maintained. Include all the ways in which data could be used.*]

Your study data will be handled as confidentially as possible. If results of this study are published or presented, individual names and other personally identifiable information will not be used *[if appropriate, add phrase such as "*unless you give explicit permission for this below*"]*

To minimize risks to confidentiality, we will: [*state how data will be stored, who will have access to the research data, what kinds of codes or encryption will be used to store and/or separate the research data from subject identifiers, if/when these materials will be de-identified and/or destroyed.*]

*State the persons or agencies (e.g., funding agency) who could have access to the participant’s information****in the present and future****, how it may be used, and the purpose of the disclosure.]*

Your personal information may be released if required by law. Authorized representatives from the following organizations may review your research data for purposes such as monitoring or managing the conduct of this study:

* Sponsor [*List Sponsor(s), as applicable*] or funding agency
* University of California

***Note: Any research data that will be linked to individual identifiers is considered identifiable****.*

 *The following language****must be****included in all studies that collect* ***identifiable information or identifiable biospecimens****:]*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, but we will take steps to protect your information. [*And one of the following:*]

* We may use or share your research information for future research studies. If we share your information with other researchers it will be de-identified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for future use of your de-identified data. OR
* Data from this study will NOT be shared with researchers or used in future research studies, even if we completely remove all identifiers, such as your name, date of birth, locations, or other personal identifying information.

[***Note:*** ***If the latter option is added to the consent form, no data or biospecimens from the study can be shared or used in future research,******even if de-identified****.* ***The IRB does not recommend use of this latter statement as it will preclude the secondary use of data in the future.*]**

*If you will be retaining the information or biospecimens in an****identifiable format****for storing, sharing, and/or other future research use, you****must****also include the following:*

1. *A description of how the information or biospecimens may be used and shared; e.g., in future research studies, repositories, conferences, presentations, etc.*
2. *You may consider allowing the participant to consent to the future use of their identifiable information or biospecimens. If you do allow participants to indicate various consent preferences, describe how the individual responses will be tracked in the RISKS Tab of the ORahs protocol application.*

We would like to use or share your identifiable information with collaborators, other researchers, or placed in a repository for future research. We will ask for your consent to do so at the end of this form. You can be a part of this current research project without agreeing to this future use of your identifiable information.

[*If you are collecting unidentifiable data, you may use the following language:*] The data we collect will not be linked to your identity in any way. We may use or share this unidentifiable data in future research studies yet to be determined.

***Confidentiality Special Considerations Section***

[*If using third party platforms to record data –State if the third party platform has access to the recorded data under their company privacy policy, terms and conditions, etc., for their own purposes*]: XXX may have access to audio and video recordings per their privacy policy. For more information on the privacy policy, please visit XXX

[*If using Focus Groups – There are special confidentiality considerations when a study involves a focus group. If audio and/or video recording the discussion, state whether the whole group must agree to be recorded, what happens if someone changes their mind about being recorded, if voices or faces will be disguised or blurred, etc.*]

We will treat all the information you say in the group discussion as confidential and we will encourage all participants to do the same. However, we cannot ensure that participants will not disclose any information to others outside of this group setting.

[*If collecting Sensitive/Reportable Research Information – If there is a reasonable expectation that reportable information may disclosed to the research during the study, then discuss how/when this information may be reported and to whom.*]

We will keep your study data as confidential as possible, with the exception of certain information that we must report to the authorities, such as child protective services for legal or ethical reasons, such as child abuse, elder abuse, or if we suspect there is an intent to harm yourself or others.

[*If the study involves collecting biospecimens/samples, genetic data, or information thereof derived from, then per the “Moore Clause”, the University of California requires the following language:*] Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.

[*If biospecimens will be discarded at the conclusion of the study AND the research team will not be sharing information thereof derived from, then include the following language:*] Biospecimens obtained will be discarded and destroyed once they have been used for the purposes described in this consent. [*If the latter option is added to the consent form, no data or biospecimens from the study can be shared,****even if de-identified****.*]

[*If the study involves genetic testing, include the following language:*]

As part of the study, we will do genetic testing or access genetic information. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may also include genetically modifying cells that are derived from your tissues to better understand how genes function.  Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, reactions to medications, and responses to treatment.

A Federal law, called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and employers of 15 or more persons to discriminate against you based on your genetic information. This means that they may not use your genetic information when making decisions regarding insurability. GINA does not, however, protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

[*Indicate whether or not clinically relevant individual results will be given to the participant, and if so, under what conditions. If there is a potential for incidental findings, describe how incidental findings will be managed and whether the findings will or will not be communicated to the participant:*]

Tests done for this study are not meant to provide clinical information and we have not intention to make any medical diagnosis. We will [*not*] provide you with any individual research results.

There is a slight possibility that during the course of the [*MRI scans, EKG tests, etc*.] that we could discover something that may affect your health. If any incidental abnormalities are discovered, you will be contacted by the investigator.

[*Indicate how new information that is learned during the study that might affect an individual’s decision to participate will be communicated:*]

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

***NIH Funded Studies:***

[*If the study is* ***funded by NIH*** *and* ***collects sensitive information*** *(e.g., illegal activities, use of illegal substance, undocumented immigrant status, etc.) then include Certificate of Confidentiality language:]*

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, 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.

*Exceptions*: A Certificate of Confidentiality does not prevent researchers from voluntarily disclosing certain information about you for legal or ethical reasons. For example, we will report information about child abuse, elder abuse, or intent to hurt yourself or others. If an insurer, employer, or other person obtains your written consent to receive research information, we cannot use the Certificate to withhold that information. In addition, the Certificate may not be used to withhold information from the federal government needed for auditing or evaluating federally funded projects or information needed by the FDA, e.g., for quality assurance or data analysis.*]*

[*State under what circumstances the data and/or biospecimens may be shared and placed into a data repository and whether any identifiers will be associated with the data and/or biospecimens*]: If you agree to take part in this study, your [*describe type of data, specimens, genetic, health information to be stored*] will be placed into one or more publicly-accessible scientific databases. For example, the National Institutes of Health (an agency of the federal government) maintains a database called “dbGaP.”  Your name and other information that could directly identify you (such as your name, address, or social security number) will never be placed into these external databases.  Other researchers may access these databases and use your data for future research, which may be about similar diseases, conditions, or may be completely unrelated to the current study.

[*If the study is considered a clinical trial**then include:*]

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 Web site will include a summary of the results. You can search this Web site at any time.

**Alternatives:**

[*If extra credit for a class is given, provide an explanation of the non-research alternative for earning equivalent credit. Describe alternative procedures or treatments that might be considered by the subject.* *If the study does not involve therapeutic or diagnostic procedures, this section may be omitted*.]

**Costs/Payments Section:**

[*Describe any costs/payments/reimbursements, the amount and method of payment. Payments must allow for pro-rating as the subject may withdraw before completion of the study and the subject is entitled to receive partial compensation appropriate for what s/he has undergone.* ]

You will be paid [*$XXX, receive a gift-card, course credit, etc*.] for taking part in this study.

[*If social security numbers are required to process payments to research subjects, explain why the information must be collected and how the information will be protected. For more information see the guidance:* [*https://www.research.ucsb.edu/compliance/human-subjects/faq#SSNs*](https://www.research.ucsb.edu/compliance/human-subjects/faq#SSNs)]

[*If payment is in the form of entry into a “drawing”, please see the guidance here* [*https://www.research.ucsb.edu/compliance/human-subjects/faq#lotteryorraffle*](https://www.research.ucsb.edu/compliance/human-subjects/faq#lotteryorraffle)*]*

[*If there will be no payment:*] You will not be paid for taking part in this study.

**Emergency Care and Treatment for Injury:**

[*If the study involves greater than minimal risk, the following statement is required by UCOP:*]

It is important that you promptly tell the researcher, [*investigator’s name*], 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/them at [*telephone number*].

If you are injured as a result of taking part in this study, University of California will provide necessary medical treatment. The costs of the treatment may be billed to your insurer just like other medical costs, or covered by the University of California or the study sponsor [*sponsor name*], depending upon a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information, email HSC at hsc@research.ucsb.edu.

**Right to Refuse or Withdraw:**

Participation is voluntary. You can refuse to take part in this project and you can stop participating at any time. You can skip questions or refuse to any questions you do not wish to answer.

[*If participants were recruited through an organization, class, or workplace, state*:] Your decision of whether or not to participate in this research will not affect your standing in [*your class, workplace, group, organization*].

**Investigator Disclosure of Personal and Financial Interests in the Research:**

[*If any members of the research team have disclosed a financial conflict of interest for the research study AND the Conflict of Interest Committee has reviewed the disclosure AND indicated there is a potential conflict of interest, participants must be made aware of this, so they can make an informed decision on whether to participate in the research. If the study does not involve an identified financial conflict of interest, then this section may be omitted.*]

**Contact Information:**

​ If you have questions about the research, you can call me at [*insert contact information (email address and phone number)*] or [*insert course teacher or advisor information*].

If you have any questions regarding your rights as a research subject, please contact the Human Subjects Committee at (805) 893-3807 or hsc@research.ucsb.edu. Or write to the University of California, Human Subjects Committee, Office of Research, Santa Barbara, CA 93106-2050

**Consent to Participate in the Research:**

By signing this document, you are agreeing to be in this study. Please make sure you understand what the study is and ask any questions before you agree to participate. [*I/We*] will give you a copy of the consent document for your records. If you have any questions about the study, please contact the investigators using the contact information in the section above.

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Name (print)

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

Signature

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

Date

**Optional Consent:**

[*Delete all sections that are not-applicable. Separate consent should be obtained for optional study activities or procedures. Optional activities must be clearly described in the Procedures section of the consent document. Examples of potential optional activities include the future use of identifiable information, use of video/audio/images in publications, presentations, etc., contacting for future studies, etc* ]

**Consent to be [Audio/Video-recorded/Photographed]:**

[*If the procedures involve audio-visual recording, participants should be asked for their permission to be recorded:*]

As part of this study, we would like your permission to [audio/video-record, take pictures]. You can still participate in the study even if you do not agree to be [audio/video recorded, photographed.]

(Check One):

\_\_\_ Yes I agree to be [specify recording type]

\_\_\_ No I do not agree to be [specify recording type]

**Consent to Use of Videos, Audio, or Images For Publications, Presentations or Educational Purposes:**

We would also like your permission to use [audio/video-recordings, photographs] of you in publications, presentations, or for educational purposes.

(Check One):

\_\_\_ Yes

\_\_\_ No

**Consent to Use and/or Share Identifiable Information for Future Research:**

[*This section is not necessary if you will only store and share de-identified data for future use.* *If requesting consent from participants for future unspecified use of identifiable information, state*]:

We would like to keep your identifiable information for future research that may be similar or completely different from this research project. Identifiable means that the data will contain information that can be used to directly identify you. The study team will not contact you for additional consent to this future use. We may also share your identifiable information with other researchers. You can contact us any time to ask us to stop using your information. However, we will not be able to take back your information from research projects that have already used it.

(Check One):

 \_\_\_ Yes I agree to let the researcher(s) use or share my personally identifiable information for future research

\_\_\_\_ No I do not agree to let the researcher(s) use or share my personally identifiable information for future research

**Consent to be Contacted for Participation in Future Research:**

[*If requesting contact information from participants for potential participation in additional research studies, state*]:

We would like to keep your contact information to invite you to be in future research studies that may be similar or completely different from this research.

(Check One):

\_\_\_ Yes I agree to let the researchers contact me for future research projects

\_\_\_ No I do not agree to let the researchers contact me for future research projects