**Consent to Participate in a Research Study (Behavioral Component)**

**Title of the Project: Sample Consent Document for Behavioral Study using the Approved Routine fMRI Protocol**

**Principal Investigator: [name, credentials, institutional affiliation]**

**Co-investigator: [name, credentials, institutional affiliation]**

**Faculty Advisor: [name, credentials, institutional affiliation]**

**Invitation to Participate in a Research Study**

We/Iinvite you to be part of a research study about **[topic and purpose]**. The study is funded by **[full sponsor name(s), if any]**. You must be 18 or over to participate in this study.

**This consent document consists of two separate parts: 1) A description of the specific research activities you are asked to participate in; 2) An fMRI informed consent that discusses the fMRI scanning process and inclusion of your fMRI images in a research repository.**

**Description of Your Involvement**

If you agree to be part of the research study, we/I will ask you to **[details].**

Provide a concise description of the research including the expected duration of the subject’s participation, description of research and/or experimental procedures that you will ask the subject to do, and the time commitment for the research and/or experimental procedures. Refer the participant to the fMRI consent document for detailed procedures associated with the scanning protocol.

**Benefits of Participation**

You may directly benefit from being in this study because **[details].**

Many behavioral studies do not offer a direct benefit to participants. Incentives to participate are not considered benefits. Information about incentives should be included within the Compensation for Participation section.

**OR**

Although you may not directly benefit from being in this study, others may benefit because **[details].**

**Risks and Discomforts of Participation**

There may be some risk or discomfort from your participation in this research. For information about risks or discomforts associated with fMRI scanning, see Section 5 of the fMRI consent document. In addition, **[list the specific risk(s) and discomfort(s) associated with the research in general and describe what you will do to minimize these].**

If a data breach, accidental or forced disclosure of research data/information could pose a risk to subjects, you should describe this risk and discuss the measures that you will take to protect the data within this section.

**Compensation for Participation**

For your participation in this research project, you will receive **[details].**

Describe the compensation or incentive for individual activities, if applicable. Note the total compensation that could be earned. Describe how compensation will be determined if the subject withdraws from the research prior to its completion. Clearly describe, if applicable, what costs are the responsibility of the subject’s to pay and what services they might receive that are gratis (such as parking).

For subject pool participants, include information regarding the amount of credit that will be offered as well as information regarding the alternative assignment.

**If compensation is more than $100 in a calendar year, you must include the following text:**

Because this study pays more than $100, the University of Michigan will collect your name, address, social security number and payment amount. This information will be safely stored and used for income tax reporting purposes only if your total payments from the University of Michigan are greater than $600 in a calendar year (January through December). If you receive more than $600 in payments from the University of Michigan in a calendar year, this information will be submitted to the Internal Revenue Service (IRS) for tax reporting purposes and an extra tax form (Form 1099) will be sent to your home. If you are a University of Michigan employee, your research payments are tracked separately and are not included as part of your payroll.

**Confidentiality**

We/I plan to publish the results of this study. We/I will not include any information that would identify you. Your privacy will be protected and your research records will be confidential.

It is possible that other people may need to see the information you give us as part of the study, such as organizations responsible for making sure the research is done safely and properly like the University of Michigan, government offices or the study sponsor, **[sponsor name(s), if any]**.

If you will obtain a Certificate of Confidentiality (CoC) for the research, insert the required CoC boilerplate text here (required text can be found at the NIH CoC Kiosk).

If you will have limits to confidentiality, describe those limitations. For example, include the following sentence **only** if you might encounter these concerns and are able to make a report:

Also, if you tell us something that makes us believe that you or others have been or may be physically harmed we may report that information to the appropriate agencies.

**Storage and Future Use of Data**

I/We will store your data/specimens **[why and how, duration, who has access, and time reference for destruction of data or specimens, if applicable].** The fMRI consent document seeks separate permission for the retention of your fMRI scans for future research.

**Sample text:** We will store your data to use for future research studies. Your name and any other identifying information will be secured and stored separately from your research data at the [name of unit]. Research data may be shared with other investigators but will never contain any information that could identify you.

**Voluntary Nature of the Study**

Participating in this study is completely voluntary. Even if you decide to participate now, you may change your mind and stop at any time**. [For projects involving survey/interview/focus groups, include: You do not have to answer a question you do not want to answer. Just tell me/us and I/we will go to the next question.]** If you decide to withdraw before this study is completed, **[details about disposition of data].**

**Contact Information for the Study Team**

If you have questions about this research, including questions about scheduling or your compensation for participating, you may contact **[PI name, contact info for PI (and faculty advisor, if PI is a student)].**

**Contact Information for Questions about Your Rights as a Research Participant**

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the:

University of Michigan Health Sciences and Behavioral Sciences Institutional Review Board

2800 Plymouth Road

Building 520, Room 1169

Ann Arbor, MI 48109-2800

Phone: (734) 936-0933 or toll free, (866) 936-0933

Email: irbhsbs@umich.edu

If you have questions or concerns about the fMRI scanning part of this research, see Part 10 of the fMRI informed consent.

**Consent**

By signing this document, you are agreeing to be in the study. I/we will give you a copy of this document for your records. I/we will keep one copy with the study records. Be sure that I/we have answered any questions you have about the study and that you understand what you are being asked to do. You may contact the researcher if you think of a question later.

*I agree to participate in the study.*

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Printed Name

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

Signature Date

You may also need to obtain separate consent for some of the more common activities listed below. Consent for specific activities should occur when the activity indicated is optional. If not optional, then this should be clearly described in the main body of the consent document.

Consent to be Audio/video Recorded

*I agree to be audio/video recorded.* ***YES\_\_\_\_\_\_\_\_\_NO\_\_\_\_\_\_\_\_\_***

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

Signature

Consent to Use Data/Specimens in Future Research

*I agree that my data/specimens may be used in future research.* ***YES\_\_\_\_\_\_\_\_\_ NO\_\_\_\_\_\_\_\_\_***

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

Signature

Consent to be Conacted for Participation in Future Research

*I agree to be contacted for participation in future research.* ***YES\_\_\_\_\_\_\_\_\_ NO\_\_\_\_\_\_\_\_\_***

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

Signature

Consent to Use Genetic Information for Future Research

*My genetic information may be used for future research.* ***YES\_\_\_\_\_\_\_\_\_ NO\_\_\_\_\_\_\_\_\_***

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Signature