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| ***HRP-518 - Template - Social Science - Behavioral Consent Document******Notes To Researcher When Using This Template**** *Italicized text is instructional language and should be DELETED from the final consent form. DELETE this table from final consent document.*
* Standard text (non-italicized) is language that can be directly used or directly inserted.
* *Use only those statements that are appropriate – this template gives many different possibilities for many types of research, thus not all the statements are relevant for all projects.*
* *Please use the appropriate headings to separate each section.*
* *The size of a consent form may vary from one to several pages depending on study complexity.*
* *If you study involves obtaining biospecimens, if the study might generate clinically relevant research results, or involves genetic testing, see the biomedical consent form for additional consent requirements.*
* *There MUST be at least a 1.5 inch margin at the bottom of each page so the IRB footer can be placed on the IRB-approved consent document. Include any information such as page numbers in the top margins.*
* *CLICK™ IRB*
	+ *Upload consent document(s) to the Consent Forms and Recruitment Materials SmartForm page*

*V19-01 (1-20-2019)* |

# Research Participant Information and Consent Form

Study Title:

Researcher and Title:

Department and Institution:

Contact Information:

Sponsor:

**BRIEF SUMMARY *(This is a general informed consent requirement)***

You are being asked to participate in a research study. Researchers are required to provide a consent form to inform you about the research study, to convey that participation is voluntary, to explain risks and benefits of participation including why you might or might not want to participate, and to empower you to make an informed decision. You should feel free to discuss and ask the researchers any questions you may have.

You are being asked to participate in a research study of ... Your participation in this study will take about \_\_\_\_\_\_. (min., hours, wks, mos, or yrs.). You will be asked to ... Include ONLY if applicable: If you decide not to take part in this research study, you should know that there are other standard or alternative treatments that may be helpful in treating your condition. They include…(

The most likely risks of participating in this study are ...

The potential benefits to you for taking part in this study are … (*describe potential benefits*) **OR** You will not directly benefit from your participation in this study. However, your participation in this study may contribute to the understanding....

*Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. In general, the beginning of an informed consent would include a concise and brief explanation of the following:*

* *(1) the fact that consent is being sought for research and that participation is voluntary;*
* *(2) the purposes of the research, the expected duration of the prospective subject’s participation, and the procedures to be followed in the research;*
* *(3) any reasonably foreseeable risks or discomforts to the prospective subject;*
* *(4) any benefits to the prospective subject or to others that may reasonably be expected from the research; and*
* *(5) appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.*
* *The information included in the brief summary typically need not be repeated later in the body of the informed consent.*
* *This summary must be kept short.*
* *See Guidance on the New Informed Consent Requirement for a Concise and Focused Presentation of Key Information for more information.*

**PURPOSE OF RESEARCH** ***(This is a required element of consent)***

* *The information included in the brief summary typically need not be repeated later in the body of the informed consent.*
* You are being asked to participate in a research study of… (include if there is additional information not included in the summary)
* You have been selected as a possible participant in this study because…
* From this study, the researchers hope to learn…*(brief summary of project)*
* Your participation in this study will take about \_\_\_\_\_\_. *(min., hours, wks, mos, or yrs.) (include if there is additional information not included in the summary)*
* *If appropriate:*
	+ *Discuss how the researcher got the subject’s name.*
	+ If you are under 18, you cannot be in this study without parental permission.
	+ In the entire study, \_\_\_\_ people are being asked to participate. *(provide number)*
	+ *List any cooperating institutions (e.g.,*This study is being conducted collaboratively by Institution A and Institution B.*).*
	+ *If your study involves incomplete disclosure or deception, the purpose section may be modified so as not to reveal the true purpose of the study. An alteration of consent must be approved by the IRB. Submit a debriefing form to be given to the subjects that explains the true purpose of the study. Often times during the debriefing process subjects are asked to re-consent to the research.*

**WHAT YOU WILL BE ASKED TO DO *(This is a required element of consent)***

* *The information included in the brief summary typically need not be repeated later in the body of the informed consent.*
* *Discuss what, if anything, the subjects have to do, not do in the study. Clearly delineate what is being done for research. For example, for education research, discuss what the subject has to do for the research and what is done for routine class work.*
* *Describe the procedures chronologically.*
* *If appropriate:*
* *If your questions are going to be sensitive in nature, tell subjects about the types of questions they are going to encounter.*
* *Tell subject if you are going to provide them with any or all findings.*
	+ *If the research involves genetic testing, see the biomedical consent template.*

**POTENTIAL BENEFITS** ***(This is a required element of consent)***

* *The information included in the brief summary typically need not be repeated later in the body of the informed consent.*
* The potential benefits to you for taking part in this study are…(*describe potential benefits*) **OR** You will not directly benefit from your participation in this study. However, your participation in this study may contribute to the understanding....(*describe overall potential benefits*) (include if there is additional information not included in the summary)
* *Financial compensation, course credit, or other forms of compensation are not considered a benefit of being in the project. This information belongs under heading, Costs and Compensation for Being in the Study.*

**POTENTIAL RISKS** ***(This is a required element of consent)***

* *The information included in the brief summary typically need not be repeated later in the body of the informed consent.*
* The potential risks of participating in this study are… **OR** There are no foreseeable risks associated with participation in this study. (include if there is additional information not included in the summary)
	+ *Include risks in addition to physical risks, for example, legal, employment, psychological, social, economic, reputation, etc.*
	+ *Include risks associated with sensitive questions, for example, breach of confidentiality, or personal distress, or discomfort.*
	+ *Include risks of reporting illegal or compromising activities (e.g. sexual behavior).*
* *If appropriate:*
	+ *If the risk is breach of confidentiality, address ways you are going to keep data confidential in the privacy and confidentiality section of the consent form.*
	+ *Discuss the availability of referrals, counseling, or other services (e.g. suicide counseling).*
	+ *For genetic testing, refer to Heading 5 in the biomedical consent template.*

**PRIVACY AND CONFIDENTIALITY** ***(This is a required element of consent)***

* *Discuss how you will maintain the subject’s privacy throughout the project (e.g. private conversations).*
* The data for this project are being collected anonymously. Neither the researchers nor anyone else will be able to link data to you.**OR** The data for this project will be kept confidential.
	+ *If the data are being coded and a key maintained separately, inform the subjects of the process.*
	+ *If the data is identifiable (even if you are using a code), it is important to tell the subjects exactly who has access to the data and how you are going to protect their privacy and/or confidentiality)*
* Information about you will be kept confidential to the maximum extent allowable by law….***OR*** *something equivalent such as,* Although we will make every effort to keep your data confidential there are certain times, such as a court order, where we may have to disclose your data.
* *Discuss how you will keep the information about the subject confidential.*
	+ *Where will the data be stored and how will it be protected?*
		- *If the data are being sent somewhere else (e.g. central data base, another institution), discuss.*
		- *If the data are being de-identified, discuss.*
		- *If you were to leave MSU, would you take a copy of the data with you? If yes, do not make the storage specific to MSU.*
	+ *Who will have access to the data? The following entities must be listed:*
		- *Researchers and Research Staff.*
		- *Institutional Review Board (IRB).*
		- *Sponsors, agencies if applicable.- list names of organizations.*
* If appropriate:
	+ *In some studies you should discuss required reporting (e.g. child abuse, elder abuse, MSU mandatory reporting protocols) or other circumstances under which their information will be released (e.g. suicide or homicide)…*unless there is a danger to yourself or others.
	+ *For education projects, discuss how the instructors/teachers cannot access identifiable data.*
* The results of this study may be published or presented at professional meetings, but the identities of all research participants will remain anonymous.
* *If data are being collected via the internet, discuss if the data are being collected anonymously or with identifiers. Tell the subject if you are collecting IP addresses or not.*
* *Certificates of Confidentiality are issued by the NIH to protect identifiable research information from forced disclosure. If a Certificate of Confidentiality is in effect, it should be reflected in the consent form. Participants should be given a fair and clear explanation of the protection that it affords, including limitations and exceptions [grants.nih.gov].*

**Your rights to participate, say no, or withdraw** ***(This is a required element of consent)***

* Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.
* You have the right to say no.
* You may change your mind at any time and withdraw.
* You may choose not to answer specific questions or to stop participating at any time.
* *If appropriate:*
	+ Choosing not to participate or withdrawing from this study will not make any difference in the quality of any services you may receive.
	+ Whether you choose to participate or not will have no effect on your grade or evaluation.
	+ You will be told of any significant findings that develop during the course of the study that may influence your willingness to continue to participate in the research.
	+ *Provide subject with the possible consequences of withdrawal or incomplete participation, and any instructions associated with the withdrawal.*

**COSTS AND COMPENSATION FOR BEING IN THE STUDY** ***(This is a required element of consent)***

* *If appropriate:*
* *Discuss any costs to the subject.*
	+ Procedures being performed for research purposes only will be provided free of charge by…
* *Discuss any compensation (amount, timing) to the subject.*
	+ You will be compensated….
	+ You will receive…
	+ You will not receive money or any other form of compensation for participating in this study.
* *For research on students, tell the subject if they will receive credit or extra credit and include amount.*
* *Note for researchers: lotteries, drawings, or raffles may require a state gaming license by law.*

**Alternative Options *(If applicable, this is a required element of consent)***

* *The information included in the brief summary typically need not be repeated later in the body of the informed consent.*
* *If appropriate:*
	+ *Discuss any alternatives to being in the research.*
	+ *If students are required to obtain research credits, inform them of the equivalent, non-research assignment which may be done in place of research participation.*

**HOW TO GET HELP IF INJURED*****(If applicable, this is a required element of consent)***

* *If appropriate, see the biomedical consent template.*

**RESEARCH RESULTS *(Include only if applicable)***

* *If appropriate:*
	+ *Tell subject if you are going to provide them with any or all findings (e.g. study findings, incidental findings for an individual subject).*

**future research (*This is a required element for any research that involves the collection of identifiable private information or identifiable biospecimens)***

* **Must include one of the two statements:**
	+ Information that identifies you might be removed from the [*describe the identifiable private information or identifiable biospecimens*]. After such removal, the [*describe the information or biospecimens*] could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you [*or your legally authorized representative*].
	+ Your [*describe the information or biospecimens*] collected as part of the research, even if information that identifies you is removed, will not be used or distributed for future research studies.

**Conflict of INterest *(Include only if applicable)***

* *If appropriate (If there is a conflict of interest), the researcher should disclose this on the consent form (e.g. Significant financial interests, Affiliation with sponsor).*

**Contact Information *(This is a required element of consent)***

If you have concerns or questions about this study, such as scientific issues, how to do any part of it, or to report an injury, please contact the researcher (name and complete contact information: mailing address, e-mail address, phone number).

If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University’s Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or e-mail irb@msu.edu or regular mail at 4000 Collins Rd, Suite 136, Lansing, MI 48910.

**Documentation of Informed consent.**

Your signature below means that you voluntarily agree to participate in this research study.

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

Signature Date

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

Signature of Assenting Child (13-17; if appropriate) Date

You will be given a copy of this form to keep.

***A signature is a required element of consent – if not included, a waiver of documentation must be granted by the IRB.***

***13. IF APPROPRIATE***

* *If subjects will be identified, specific permission for identification must be obtained.*
	+ I agree to allow my identity to be disclosed in reports and presentations.

[ ]  Yes [ ]  No Initials\_\_\_\_\_\_\_\_\_\_\_\_

* *Inform subjects if they are being audiotaped or videotaped – indicate if this is required to be in the project, if not required, a separate check box with signature or initials is appropriate.*
	+ I agree to allow audiotaping/videotaping of the interview.

[ ]  Yes [ ]  No Initials\_\_\_\_\_\_\_\_\_\_\_\_

* *Discuss how the tapes will be stored, protected, and when erased or destroyed.*