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| **HRP-502 - Template - Minimal Risk Consent Document**  **Informed Consent Template for Minimal Risk Research**  **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 form.* * 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.* * *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.* * *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.* * *CLICK™ IRB*   + *Upload consent document(s) to the Consent Forms and Recruitment Materials Smartform page*   *V19-01 (1-21-2019)* |

# 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.*

The purpose of this research study is *[give a general description of the project-what is being investigated, what is the hypothesis, what knowledge is being sought and why]. (include if there is additional information not included in the summary)*

**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.*

*[Describe the procedures/process in chronological order, define and explain all technical terms.]*

*[Identify and explain any procedures that are experimental] (include if there is additional information not included in the summary)*

*[Explain tasks, surveys, interviews or procedures; describe the assignment to control or experimental groups, length of time for participation, frequency of procedures, location etc.]*

*[If the study involves surveys or questionnaires, include a statement that the subject is free to skip any questions that he/she would prefer not to answer.]*

**POTENTIAL BENEFITS** ***(This is a required element of consent if there are any potential benefits)***

*• The information included in the brief summary typically need not be repeated later in the body of the informed consent.*

*You [may not/will not] benefit personally from being in this study. However, we hope that, in the future, other people might benefit from this study because [describe why others might benefit in the future in terms of the knowledge that will be gained]. Compensation/extra credit is not a benefit and should not be listed as a benefit.] (include if there is additional information not included in the summary)*

**POTENTIAL RISKS** ***(This is a required element of consent if there are any potential risks)***

*[Describe the risks-psychological, emotional, physical, legal, privacy issues, etc. Depending on the type of study, some risks may be better described as things that could make the subject “uncomfortable” –such a fatigue or embarrassment.. If there are no known risks, state that there are “no foreseeable risks” to participating] (include if there is additional information not included in the summary)*

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

*[Include how long data and identifying information including signed consent forms will be kept. Be sure to address security measures for both physical data and electronic data. If you are video or audio-recording information about the individual, indicate how long those recordings will be kept include information on if and when they will be destroyed. It is important to tell the person if these recordings will be used for other purposes than this research, e.g., teaching, presentations, etc. It should also be explained, where applicable, that the information may be stripped of identifiers and used in future research without anyone knowing it is information from the participant.* *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.]*

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

You have the right to say no to participate in the research. You can stop at any time after it has already started. There will be no consequences if you stop and you will not be criticized. You will not lose any benefits that you normally receive.

**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)***

* *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.*

**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](mailto: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.

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Signature Date

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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.***

***12. 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.*