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| ***HRP-517 - Template - Biomedical Consent Document***  ***Notes To Researcher When Using This Template***   * *Italicized text is instructional language and should be DELETED from the final consent document. 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 studies.* * *Please use the appropriate headings to separate each section.* * *The size of a consent document 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.* * *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 granted 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.*

**Alternative Options *(This is a required element of consent only if alternatives exist)***

* *The information included in the brief summary typically need not be repeated later in the body of the informed consent.*
* 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…(*include record of success of standard treatments*) *(include if there is additional information not included in the summary)*
* If you decide to participate in this study, you may ask Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ to discuss these alternatives with you again at any time during 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.*
* Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and his/her associates will…*(include if there is additional information not included in the summary)*
* *Discuss what, if anything, the subjects have to do/ not do in the study. Clearly delineate what is being done for research and what is being done as part of standard care*
* *Describe the procedures chronologically.*
* *Discuss any special precautions (e.g. medication may make you drowsy...)*
* *Discuss randomization and placebos as appropriate.*
* The patients in the study will be assigned by random, that is, by a method of chance, to one of the groups. You will have an equal chance of being in either group of the study (e.g. active drug vs. placebo, one drug vs. another drug).
* This study is blinded. Neither you nor your physician will know what group you are in.
* This is a placebo controlled study. There will be 2 (or more) groups of patients. One or more groups will receive the experimental drug; the other groups will receive a placebo. A placebo is an inactive substance which will have no direct effect on your illness.
* *This is a required element of consent for research involving biospecimens that might generate whole genome sequencing:*
  + This research will or might include whole genome sequencing. Whole genome sequencing is [*insert lay person definition*].

**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 or other compensation is not considered a benefit of being in the project. This information belongs under heading 8, 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… *(include if there is additional information not included in the summary)*
  + *Include risks other than physical risk, for example, legal, employment, psychological, social, economic, reputation, etc. or,* There are no foreseeable risks associated with participation in this study.
  + *List side effects with rates and pertinent details.*
  + *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:*
  + There may be additional risks that are currently unforeseeable.
  + *Discuss risks to pregnant women, unborn babies, and breastfeeding women.*
    - If you were to, or might, become pregnant, the research might involve risks to the embryo or fetus that are currently unforeseeable.
    - There may be additional risks to pregnant women, fetuses, or embryos that are currently unforeseeable.
  + *Discuss reproductive risks to men and women.*
  + *Discuss the availability of referrals, counseling, or other services (e.g. suicide counseling).*
  + *For genetic testing, can results be damaging to the subjects in terms of insurability, employability, etc.*
    - The knowledge obtained about you from the genetic testing poses no risks to you.
    - The knowledge obtained about you from the genetic testing may put you at risk for…..

**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 study 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.
* 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 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)*
    - *For FDA regulated research, the consent form must include:* There is a possibility that the U.S. Food and Drug Administration may inspect the records.
    - *Sponsors, agencies if applicable, etc.- list names of organizations.*
    - *FDA requires that informed consent documents and processes for applicable drug (including biological products) and device clinical trials include a specific statement that clinical trial   
      information will be entered into a databank. The databank referred to in this final rule is the clinical trial registry databank maintained by the National Institutes of Health/National Library of Medicine (NIH/NLM) Include the following language if applicable:*
      * “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.”
* 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.
  + The results of this study may be published or presented at professional meetings, but the identities of all research participants will remain anonymous.
  + *If the data are being coded and a key maintained separately, inform the subjects of the process.*
  + *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 treatment you may receive.
* Whether you choose to participate or not will have no affect on your grade, evaluation or medical care.
* 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 and any instructions associated with the withdrawal.*
* *If there are circumstances where the researchers may terminate participation (with regard to consent), describe.*
* *If there are circumstances where a subject may partially withdraw (e.g. withdraw from the intervention but agree to continued follow-up) explanation of these options should be provided. Separate, additional consent for this limited participation in the study is required.*

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

* *This is a required element of consent if the research involves biospecimens:*
  + Your [*describe the biospecimens*], even if information that identifies you is removed, may be used [to make money. You [*will, will not*] share in this money.
* *If appropriate:*
* *Discuss any costs to the subject (choose appropriate option below, if applicable).*
  + - Procedures being performed for research purposes only will be billed to your insurance company. As with any medical insurance, any costs in excess of what is paid by your insurance or other third party payer will be your responsibility.
    - 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.
* *Note for researchers: lotteries, drawings or raffles may require a state gaming license by law.*

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

* *If appropriate, include one of the following standard paragraphs:*
* *No costs will be paid.*

If you are injured as a result of your participation in this research project, Michigan State University will assist you in obtaining emergency care, if necessary, for your research related injuries. If you have commercial insurance for medical care, your insurance carrier will be billed in the ordinary manner. As with any medical insurance, any costs that are not covered or in excess of what are paid by your insurance, including deductibles, will be your responsibility. The University’s policy is not to provide financial compensation for lost wages, disability, pain or discomfort, unless required by law to do so. This does not mean that you are giving up any legal rights you may have. You may contact *[insert Principal Researcher’s name and phone number]* with any questions or to report an injury.

* *Third party will pay.*

If you are injured as a result of your participation in this research project, Michigan State University will assist you in obtaining emergency care, if necessary, for your research related injuries. If you have commercial insurance for medical care, your insurance carrier will be billed in the ordinary manner. Any costs that are not covered or in excess of what are paid by your insurance, including deductibles, shall be paid by *[name of payee]*. The University’s policy is not to provide financial compensation for lost wages, disability, pain or discomfort, unless required by law to do so. This does not mean that you are giving up any legal rights you may have. You may contact *[insert Principal Researcher’s name and phone number]* with any questions or to report an injury.

* *Alternative Injury Clause Language.*

*For projects that are funded - If the sponsor has requirements different or in addition to the statements above (i.e., U.S. Army), language will be negotiated with the IRB and other appropriate individuals (e.g., responsible project researcher, department, sponsor, legal counsel). In any case, “no informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the researcher, the sponsor, the institution or its agents from liability for negligence.” (45 CFR 46.116, 21 CFR 50.20)*

* *If the study is not being performed at MSU facilities or is being performed by non-MSU researchers, the injury clause should state who will be responsible for providing emergency care and who will be responsible to pay for this treatment. A variation of the MSU clause above may be appropriate.*

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

* *This is a required element of consent when the study could involve clinically relevant research results.*
  + There may be results of the research that may be relevant to your clinical care. You will be told of [*describe the results*] when [*describe when*]. *AND/OR* You will not be told of [*describe the results*]. *(this may be a combination of being told some results but not others)*
* *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).*
  + *If genetic testing, will the subject be told of the results? If yes (explain): will the results make the subjects upset? Will counseling be offered? How will counseling be paid for?*

**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 (i.e. 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.

**12. 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, unless the IRB grants a waiver of the requirement to obtain a signed consent document.***

***IF APPROPRIATE***

* *If tissues, blood, fluids, or genetic material will be used for future research, separate signoff is required. The separate sign off granting that permission should appear after the signature section of the consent.*
  + *Provide the following choices:*

I agree to allow my [*tissues, blood, body fluids, DNA*] to be stored and used for future research with identifiers. I may be contacted for future studies. Initials\_\_\_\_\_\_\_\_\_\_\_\_

I agree to allow my [*tissues, blood, body fluids, DNA*] to be stored and used for future research without identifiers. I will not be contacted for future studies. Initials\_\_\_\_\_\_\_\_\_\_\_\_

I do not want my [*tissues, blood, body fluids, DNA*] to be stored and used for future research. My samples will be destroyed after this study is over. Initials\_\_\_\_\_\_\_\_\_\_\_\_

* + *Note: If the samples are stored without identifiers or linking codes, no further IRB approval is needed for future research on these samples.*
  + If future work is done on your samples beyond the scope of this project, the researchers will present the research to an Institutional Review Board to review and approve and determine if your further consent is needed.
* *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\_\_\_\_\_\_\_\_\_\_\_\_