**1.0 Participant Informed Consent**

**Title of Study:**

**Principal Investigator:**

**Co-Investigators:**

**Study Staff:**

**Sponsor:**

The (Name of Funded Institution or Awarded Individual) is conducting a research study called, “\_\_\_\_\_\_\_”. The study is funded by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

**2.0 What is the study about?**

(A brief explanation of why the study is being conducted (what you hope to learn), how many people will be in the study, why the participant has been chosen to participate (eligibility requirements.).

**3.0 How long will I be in the study?**

Your part in the study will last \_\_\_\_\_\_\_\_\_\_.

**4.0 What will happen in the study?**

(Provide an explanation of what will take place during the study and what is expected from participants. Itemize what will happen at each study visit and the expected visit length. Use bullets when appropriate. Be careful to use non-coercive language (e.g. "we will ask you to" versus "you will fill out" or "you will do the following." Explain any experimental procedures.)

If you are eligible and wish to join the study, you must sign this consent form. If you do not sign the consent form you cannot join the study.

We will review this consent form with you at/during…… You will be given enough time to review the consent and have all your questions about the study answered. We will give you a signed copy of the consent for your records (when, in person, by mail, etc.).

Study staff will not know which group or study drug/treatment you are assigned to. You should not join the study if you are not willing to take the study drug/treatment (or join the group) you are assigned to.

**5.0 What if I have questions?**

You can contact \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ at \_\_\_\_\_\_\_\_\_\_\_ if you have questions about the study. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ is in charge of the study. You may also contact \_\_\_\_\_\_\_\_\_\_\_\_\_ at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ if you have questions about the study.

(The below statement must be included verbatim if a description of your study is listed on http://www.ClinicalTrials.gov and your study involves testing a biological agent or device.)

“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.”

**6.0 Do I have to be in the study?**

(Use all statements below. White space between key statements is important.)

You decide if you want to be in the study. Deciding not to take part will not affect your relationship with your medical provider or NUNM. If your health care provider is an investigator for the study, you may get a second opinion from another doctor not involved in the study.

You can leave the study at any time and you do not have to give a reason. Leaving the study will not affect your relationship with your medical provider or NUNM.

If you are an NUNM student or employee, this study is completely voluntary. Your decision to not participate or to leave the study will not affect your relationship with NUNM.

The study investigators may ask you to leave the study if it is in your best interest. The study investigator may ask you to leave the study if you do not follow the study rules.

**7.0 What if I don’t want to be in the study?**

You can choose not to be in the study and you do not have to give a reason. You can choose to (talk to their doctor about other options, investigate outside resources on their own, etc.).

**8.0 Are there any costs?**

All study-related treatments are free. OR Your cost(s) for participating in the study would be……………… (how much, how often, overall approximate total).

**9.0 Will I be paid for being in the study?**

You will not be paid for being in the study. OR You will receive (amount, type of payment, when) as a thank you for your participation.

(If you choose to use a type of payment as incentive for obligating participant time, you must inform participants that the NUNM Business Office requires W-9 information to be submitted, including SSN.)

In order to receive the above mentioned incentive (type of payment), our business office requires each participant to submit a W-9 form (including Social Security Number) in order to process your (type of payment). If you choose not to supply this information, you may not partake in the study.

**10.0 Are there any risks?**

There is always a small risk of a breach of confidentiality to your personal health information. However, these risks have been addressed and minimized as much as is possible.

You will be told about any new information that may affect your willingness to participate in the study.

There could be risks that we are unaware of at the time of the study.

(Itemize risks to participant for all categories of involvement (e.g., physical exams, questionnaires, blood draws, study drug/treatments, etc. This may mean repeating some information from the study description.).

If you experience any side effects while on the study contact (clinical investigator name here) \_\_\_\_\_\_\_\_\_\_\_\_\_\_ at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ as soon as possible.

**11.0 What if I feel I’ve been hurt by taking part in the study?**

If you feel you have been injured or harmed by taking part in this study, please contact (principal investigator name here) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. If you feel you were harmed while taking part in this study, you may be treated at NUNM. However, NUNM does not offer to pay the cost of this treatment.

If you feel your rights have been violated or you have been harmed by this study, please contact the NUNM Institutional Review Board Chair, Dr. Richard Barrett, at 503-552-1758.

**12.0 Are there any benefits?**

(Receiving an incentive is not a benefit. Receiving free tests for an unproven treatment, etc., is not a benefit. Receiving a chest x-ray for example as part of the study could have other benefits, however.)

It is possible you may receive some benefit from …………………… There is no guarantee, however, that you will receive any benefit at all. Your participation will help us learn more about …………

**13.0 Your privacy is important**

(Most statements below are required. Modify for your study design if necessary.)

The Health Insurance Portability and Accountability Act (HIPAA) is a federal law to protect your privacy. Protecting your privacy is very important to us.

During this study we will ask about your (past) and (current) medical history, we will do this with questionnaires, medical exams, blood draws, etc. This information will be used to determine your eligibility for the study and provide data for the study. Your personal health information will be kept private and only authorized study staff will have access to this information. We will use a study number instead of your name. All paper forms will be kept in a locked, secure office. All electronic data will be stored on password-protected computers. Your name will not be used in any publications or presentations about this study.

During the study, you may not be given access to medical information about you that is part of the study. When the study is over, you may request certain medical information collected about you that is part of your study medical record.

None of your personal information will be shared outside of NUNM. OR As part of the study, we will share your information with ………………….. We will share (type of data, keep it simple and brief) in order to……………………. Agreements are in place with \_\_\_\_\_\_\_ to protect your privacy.

By signing this consent form you are stating that we can use your health information in the ways mentioned above for this study. You are not waiving any of your legal rights by signing this form.

You have the right to take away your permission to use your health information and any blood and/or tissue samples collected as part of the study. In order to do this you must send a written request to:

Investigator name, address.

Once your letter is received no additional information about you or blood or tissue samples will be collected from you for this study. Any data and/or blood and/or tissue samples that were collected before we receive your letter will continue to be used for the study. If applicable or include in a second genetic only consent: If you take away your permission to use your tissue or blood samples for a genetics research study, your samples will be destroyed or stored without any information that identifies you. Taking away your permission to use your health information will not affect your relationship with NUNM.

We are collecting only the personal health information that we need for the specific purpose of this study. Your personal health information cannot be used for additional research purposes.

NUNM may be required to provide copies of your personal information to Federal or other government agencies as required by law. It may also be required to provide copies to the Institutional Review Board (IRB) or other groups that monitor the safety and welfare of study participants.

If your personal health information is disclosed by this authorization to an individual or agency not covered by laws that prohibit re-disclosure, your personal health information may not remain confidential. However, Oregon law does not allow re-disclosure of HIV/AIDS information, mental health information, genetic information, and drug/alcohol diagnosis, treatment, or referral information.

Your permission to use your identifiable health information (your HIPAA authorization) will expire when the study is complete.

(If a part of this study includes genetic research, additional statements would be required regarding the storage, destruction, use, sharing, and timeline for that material. Otherwise, include this information in a second consent about the genetic portion only.)

**14.0 Signatures**

By signing this consent form it means the following:

• I know my rights have not been waived by signing.

• I have had all of my questions answered and I know whom to ask if I have more questions.

• I have read this form and understand it.

• I want to join the study.

• I know I can leave the study at any time and do not have to give a reason.

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Signature of Participant Date

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Printed Name of Participant

(If appropriate, add a print & signature line for parent or legal guardian with date.)

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Signature of Consenter Date

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Printed Name of Consenter

**\*\*\*Required: A signed and dated copy of this consent form will be provided to the participants the day they are consented. (ICH [2016] Section 4.8.11)\*\*\***

**Thank you for participating in our research study!**