**[Insert Study Title]**

You are being asked to participate in a research study. Researchers are required to provide a consent form such as this one to tell you about the research, to explain that taking part is voluntary, to describe the risks and benefits of participation, and to help you to make an informed decision. You should feel free to ask the researchers any questions you may have.

Principal Investigator Name and Title: [Insert name & title]

Department and Institution: [Insert department & institution]

Address and Contact Information: [Insert address & contact information]

Emergency Contact Name and Information: [Insert emergency contact name & information]

Sponsor: [required if sponsored; insert sponsor]

**Why am I being asked?**

You are being asked to be a subject in a research study about [Insert protocol-specific text].

You have been asked to participate in the research because [Insert protocol-specific text].

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future dealings with the Southwest College of Naturopathic Medicine (SCNM). **If you decide to participate, you are free to withdraw at any time without affecting that relationship.**

Approximately [Insert number] subjects may be involved in this research at the SCNM campus.

*[Include section only if applicable]***Conflict of Interest – see additional language document**

**What is the purpose of this research?**

This research is being done to better understand [Insert protocol-specific text]. ***OR***

The study is being done to test [Insert protocol-specific text].

**What procedures are involved?**

This research will be performed at [Insert protocol-specific text].

You will need to come to the study site [Insert protocol-specific text] times over the next [Insert protocol-specific text].

Each of those visits will take about [Insert protocol-specific text].

The study procedures are [Insert protocol-specific text].

**What are the potential risks and discomforts?**

There may be risks from the study that are not known at this time. [Insert protocol-specific text]. ***OR***

The likely risks and discomforts expected in this study are [Insert protocol-specific text]. ***OR***

The less likely risks and discomforts expected in this study are [Insert protocol-specific text]. ***OR***

Rare but serious risks include [Insert protocol-specific text].

“To the best of our knowledge, the things you will be doing have no more risk of harm than you would experience in everyday life.”

“A risk of this research is a loss of privacy (revealing to others that you are taking part in this study) or confidentiality (revealing information about you to others to whom you have not given permission to see this information).”

**Will I be told about new information that may affect my decision to participate?**

During the course of the study, you will be informed of any significant new research findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study may be re-obtained.

**Are there benefits to taking part in the research?**

You [Choose: will or may] not directly benefit from participation in the research. ***OR***

You may directly benefit, but no benefits are guaranteed. ***OR***

This study is not designed to benefit you directly. This study is designed to learn more about [Insert protocol-specific text]. The study results may be used to help other people in the future. ***OR***

Taking part in this research study may not benefit you personally, but we [researchers] may learn new things that will help others.

**What other options are there?**

You have the option to not participate in this study ***OR*** [Insert protocol-specific text]

**What about privacy and confidentiality?**

**Will my study-related information be kept confidential?**

Select 1 of the 3 statements that is the best applicable to your research study:

Option 1:

We will use all reasonable efforts to keep your personal information confidential, but we cannot guarantee absolute confidentiality. When this research is discussed or published, no one will know that you were in the study. But, when required by law or school policy, identifying information (including your signed consent form) may be seen or copied by:

1. The Institutional Review Board that approves research studies;
2. The Office for Protection of Research Subjects and other college departments that oversee human subjects research;
3. College and state auditors responsible for oversight of research; and
4. Federal regulatory agencies such as the Office of Human Research Protections in the Department of Health and Human Services. [If research is federally funded]

Option 2:

Faculty, students, and staff who may see your information will maintain confidentiality to the extent of laws and school policies. Personal identifiers will not be published or presented.

Option 3:

Faculty, staff, students, and others with permission or authority to see your study information will maintain its confidentiality to the extent permitted and required by laws and school policies.  The names or personal identifiers of participants will not be published or presented.

Include all of the following that are appropriate or applicable to the research study

1. The financial sponsor of the research, [Insert sponsor name, if externally funded];
2. The Food and Drug Administration [for drug or device studies];
3. The National Institutes of Health [for research funded or supported by NIH];
4. The National Cancer Institute [for research funded or supported by NCI];

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

Exception for abuse and neglect:

If you disclose actual or suspected abuse, neglect, or exploitation of a child or a disabled or elderly adult, the researcher or members of the study staff will report the information to Child Protective Services, Adult Protective Services, and/or a law enforcement agency.

*[Include section only if applicable]* **Focus group or group discussion – see additional language**

**What if I am injured as a result of my participation?**

[Insert protocol-specific text].

* *If the possibility of loss of employment, loss of insurance, psychological or emotional harm exists, you may want to include the following language:* ***\*Suggested Text\****“If you suffer from [Insert possible conditions], contact the Principal Investigator and [Insert where to seek help].”
* You may contact the researcher [Insert principal investigator] at [Insert phone number] to talk to them about your illness or injury.  [For research involving greater than minimal risk, emergency contact information should be included here]

***[This section is required when appropriate]* What if I lose the ability to make decisions during the study? – see additional language document**

[*This section only if applicable]***Studies that are considered clinical trials and requires to be entered on clinicaltrials.gov – see additional language document**

*[Include section only if applicable]* **Research shows the subject has a communicable disease, e.g., HIV/AIDS, TB – see additional language document**

**What are the costs for participating in this research?**

There are no costs to you for participating in this research. ***OR*** [Insert protocol-specific text].

**Will I be reimbursed for any of my expenses or paid for my participation in this research?**

You will not be offered payment for being in this study. ***OR***

You will receive [Insert payment amount and method of payment (i.e. cash, check, gift card)] for each completed study visit. If you do not finish the study, you will be compensated for the visits you have completed. If you complete the study, you will receive a total of $[Insert total payment amount]. You will receive your payment within approximately [Insert length of time before payment is received (i.e. immediately, within 30 days - standard unless gift card is given in person) ] [Insert payment schedule (i.e., after each visit, at the end of the study, etc.)] by [Insert payment delivery method (i.e., direct deposit, in person, mail, etc.)].

***[Include all or part of this section, as applicable]*Will my cells, tissues, blood, or other biological materials be used to develop commercial products?**

If a commercial product is developed from the tissue or blood samples collected as part of this research project, the commercial product will be owned by [Insert appropriate entity]. You will not profit financially from such a product.

Cells obtained from your body may be used to establish a cell line which may be shared in the future with other researchers and which may be of commercial value. A cell line is one which will grow indefinitely in the laboratory. Cell lines may be useful because of the characteristics of the cells and/or the products they may produce.

* *If any human materials (tumor tissue, bone marrow, blood, etc.) are used for establishing a cell line which may be shared with other researchers and which may in the future be of commercial value, the subject must be informed of the fact in the consent form.*

***[Include as applicable]***In the event you withdraw or are asked to leave the study, you will still be compensated as described above.

**Can I withdraw or be removed from the study?**

If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without affecting your future care at SCNM.

You have the right to leave a study at any time without penalty. For your safety, however, you should consider the investigator’s advice about how to leave the study. If you leave the study before the final planned study visit, the investigator may ask you to complete the final steps.

The researchers and sponsor also have the right to stop your participation in this study without your consent if:

* *They believe it is in your best interests;*
* *You were to object to any future changes that may be made in the study plan;*
* *If applicable, list any reasons specific to the study ( i.e., the sponsor of the research has decided to stop the research, if you experience a severe side effect, if you do not follow the study procedures or if new information is identified); and/ or*
* *Describe any other circumstances for withdrawal.*

**Who should I contact if I have questions?**

Contact the researchers [Insert names and titles] at [Insert phone number(s)] or email address [Insert email address(es)]:

1. if you have any questions about this study or your part in it,
2. if you feel you have had a research-related injury (or a bad reaction to the study treatment), and/or
3. if you have questions, concerns or complaints about the research.

**What are my rights as a research subject?**

If you feel you have not been treated according to the descriptions in this form, or if you have any questions about your rights as a research subject, including questions, concerns, complaints, or to offer input, you may call Yasmin Abusamra, the IRB Chair at 480-222-9361 or e-mail y.abusamra@scnm.edu

*This section if applicable:***What if I am an SCNM student? – see additional language document**

*This section if applicable:***What if I am an SCNM employee?** – see additional language document

**Remember**:

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future relations with SCNM. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research. I will be given a copy of this signed and dated form.

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

Signature Date

\_\_\_\_

Printed Name

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

Signature of Person Obtaining Consent Date (must be same as subject’s)

\_\_\_\_\_

Printed Name of Person Obtaining Consent