**Consent for Participation in Research**

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| **General Instructions****\*\*Delete this instructional table when you have completed the consent form\*\*** Instructional text and/or guidance is in *blue italic font*. Before submission, please delete this box, blue instructional text, and information in this template that does not apply to your study.* The consent form has two parts. Part I provides participants with key information to inform their decision to participate or not. Part II relays additional information or details that are not presented in Part I as needed.
* The consent form must be written in lay language using 2nd person point of view (e.g., you will be asked to submit a saliva sample). The use of jargon, including any complex terms or concepts should be avoided. All acronyms or abbreviations must be defined the first time they are used. For additional guidance, view the [PRISM Readability Toolkit](https://www.une.edu/sites/default/files/PRISMReadabilityToolkit_ThirdEdv6_062210.pdf).
* Avoid lengthy paragraphs – consider using bullet points to present information in a more user-friendly format.
* If HIPAA applies to your study, you will need to obtain prospective HIPAA authorization from the participant using the stand-alone HIPAA authorization form available on the UNE IRB [website](https://www.une.edu/research/integrity/irb).

**Contact the Office of Research Integrity at** **irb@une.edu** **if you have questions or need further assistance.** |

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| Consent Form Version Date: | *[This is the date the consent form was initially created or subsequently revised]* |
| IRB Study #: | *[An IRB Study # will be assigned to you upon receipt of your submission]* |
| Title of Study: |  |
| Funding Source: | *[Indicate ‘None’ if your study is not funded]* |
| Principal Investigator (PI): | *[There can only be one individual listed as the PI of the study]* |
| PI Contact Information: | *[Provide the UNE e-mail address and phone number of the PI]* |

* **Part I** of the consent form has been designed to provide you with key information about this study to help you decide if you would like to participate. Your decision is completely voluntary.
* Additional information and details about this study are contained within **Part II** of the consent form.
* The use of the word ‘we’ refers to the Principal Investigator and/or other research staff.

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| **PART I: KEY INFORMATION ABOUT THIS RESEARCH STUDY** |

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| **Part I Instructions** **\*\*Delete this instructional table when you have completed the consent form\*\*** * Informed consent must begin with a **concise and focused** presentation of the **key information** that is most likely to assist a participant in understanding the reasons why one might or might not want to participate in the research.
* Use Part I to relay the most crucial information about the study (see the general considerations listed in the blue table below for assistance with this activity).
* **This part of the consent form** **should not exceed 1 to 1.5 pages in length.**

**Note**: You do NOT need to provide an answer to each of the general considerations listed. These questions are intended to help you identify the key information a prospective participant may need to know about in order to make a well-informed choice about whether to participate. These questions do not represent an exhaustive list.  |

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| **WHY IS THIS RESEARCH BEING CONDUCTED?** By doing this study, we hope to learn *[insert* ***brief*** *description]*. You are being asked to participate in this study because *[include a description of the target population and/or participant selection criteria as relevant to the study]*. For additional details regarding the purpose of this study, please refer to **Part II** of the consent form *[delete this statement if not needed].****General considerations when writing the brief description for this section (not all items listed may be applicable to your study)****:** *What is the general purpose of the study?*
* *Is the study funded? If yes, by whom?*
* *What is the research question the study is trying to answer? Why is it relevant to the participant?*

**WHAT IS INVOLVED IN THIS STUDY?**Participation in this study requires *[insert* ***brief*** *description].* For additional details regarding your involvement in this study, please refer to **Part II** of the consent form *[delete this statement if not needed].****General considerations when writing the brief description for this section (not all items listed may be applicable to your study)****:** *What activities or procedures will the participant be asked to complete for this study?*
* *Are any of the procedures the participant will be asked to complete deemed experimental?*
* *Does this study involve randomization into a study group? If yes, what is the probability or chance of being randomized into a given study group?*
* *Are there any procedures or components of the study that are optional?*
* *What information about the participant will be collected as part of this research?*
* *What is the estimated amount of time the participant will be directly involved with this study? It may be helpful to provide details on the number of research activities/visits, frequency of research activities/visits, length of research activities/visits, or any other information relevant to the participant’s time commitment for this study.*
* *What aspects of research participation or this particular study are likely to be unfamiliar to a prospective participant, diverge from a participant’s expectations, or require special attention?*

**WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?**The possible benefits you may experience from being in this study include *[insert* ***brief*** *description].* For additional details regarding the potential benefits of this study, please refer to **Part II** of the consent form *[delete this statement if not needed].** *Describe the most important reason(s) why a participant may want to volunteer for this study.*
* ***Note****: compensation or incentives provided for participation is NOT considered a benefit to participants.*

*OR, if there are no direct benefits, use the following text:*There are no likely benefits to you by being in this study. However, some participants appreciate knowing they have contributed to research that may benefit others in the future.**WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?**The key reasons you may choose not to participate in this study include *[insert* ***brief*** *description].* For additional details regarding the potential risks, discomforts, or inconveniences of this study, please refer to **Part II** of the consent form *[delete this statement if not needed].****General Considerations when writing the brief description for this section (not all items listed may be applicable to your study)****:** *What are the* ***major*** *risks associated with this study? If the research poses several risks, identify only those risks with the greatest impact in terms of frequency and/or severity in this section. Additional risks not mentioned in this section should be described in Part II of the consent form.*

***Note****: Risk may include psychological, physical, legal, social/reputational, and/or economic/financial harm to participants. In qualitative research, common sources of potential harm include invasion of privacy, stigmatization, or breach of confidentiality.** *Will participation in the study result in any discomforts or inconveniences for the participant (e.g., significant time commitment required for study activities, a need to abstain from certain activities, answering sensitive questions, etc.)?*
* *Are there significant out-of-pocket expenses the participant would incur as a result of participation?*
* *Is there potential impact on non-participants (e.g., caregivers, family members, children, partners, etc.)?*

***Specific Considerations for Medical Treatment Studies****:** *Will the treatment in this study be similar to or different from the standard clinical care the participant would receive if not in this study?*
* *Will the treatment provided in this study impact the participant’s future clinical care (e.g., whether use of an experimental intervention is likely to make a standard clinical intervention ineffective or unavailable after the study)?*
* *Will access to the experimental intervention be available to the participant after the study has been completed?*
* *You may want to note that UNE makes no commitment to provide free medical care or money to participants who experience a research-related injury during the study.*

**DO YOU HAVE TO PARTICIPATE IN THIS STUDY?**If you decide to take part in this study, it should be because you really want to volunteer. You will not lose any services, benefits or rights, or access to care *[delete ‘or access to care’ if not applicable]* you would normally have if you choose not to volunteer. You will not be penalized if you choose not to volunteer for this study.*State the following if you will recruit UNE students:* Your decision to engage/not engage in this study will have no effect on your academic status, class grade(s), or relationship with any instructor(s) at UNE.*State the following if you will recruit UNE employees:* Your decision to engage/not engage in this study will have no effect on your employability or performance review at UNE.**WHAT OTHER CHOICES ARE AVAILABLE TO YOU IF YOU DON’T WANT TO PARTICIPATE IN THIS STUDY?**If you do not want to take part in this study, there are other choices such as *[insert* ***brief*** *description].** *For a medical treatment study, describe what would occur should the person choose not to participate (e.g., standard of care is available). Specify any other medical treatment options that might be available to the participant outside of the research study.*
* *For a non-medical research study, describe whether there are any activities the participant could do in order to receive the same level of benefit (e.g., if recruiting UNE students for research, offering an alternative means of earning equivalent course credit or extra credit for an equivalent commitment of time and effort if the student chooses not to participate in the research study).*

*OR*If you do not want to be in this study, there are no other choices except not to take part in the study.**WHAT IF YOU HAVE QUESTIONS ABOUT THIS STUDY?**You have the right to ask, and have answered, any questions you may have about this research (now, during, or after the study is completed). If you have questions about this study, complaints, concerns, or if a research-related injury or harm occurs, you should contact the Principal Investigator listed on the first page of this document *[and/or identify additional contact person(s) and supply contact information]*. **WHAT IF YOU HAVE QUESTIONS ABOUT YOUR RIGHTS AS A RESEARCH PARTICIPANT?**If you have questions or concerns about your rights as a research participant, or if you would like to obtain information or offer input, you may contact the UNE Office of Research Integrity at (207) 602-2244 or via e-mail at irb@une.edu. |

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| **PART II: ADDITIONAL INFORMATION & DETAILS ABOUT THIS RESEARCH STUDY** |

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| **Part II Instructions** **\*\*Delete this instructional table when you have completed the consent form\*\*** * Use Part II of the consent form to relay additional information, further explanation, or details that are not presented in Part I as needed.
* The information included in Part I does NOT need to be repeated in Part II. However, you may choose to repeat some information if it assists participant understanding of the study.
* You may delete sections within Part II of the consent form if all applicable information requested in Part II is already relayed within Part I.
* Depending on the type of study you are conducting, additional sections may need to be inserted into Part II of the consent form to meet compliance with federal regulations. Please refer to [**Appendix A**](#AppendixA)for details.
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**PURPOSE OF THE RESEARCH**

The purpose of this study is *[describe the purpose of the study]*. *If this study is funded, identify the funding source.*

**NUMBER OF PARTICIPANTS**

*[X number of participants]* people will take part in this study at the University of New England. *If this is a multi-site study being conducted at several institutions, also indicate the total number of participants who will participate across all sites within the United States or worldwide.*

**YOUR INVOLVMENT IN THIS STUDY**

You will be asked to *[insert description]*.

* *Using lay language, provide an accurate description of what the participant will be asked to do during the study.*
* *Describe where procedures will take place, and whether any procedures are deemed experimental. If applicable, include procedures for audio/video recording and/or photography.*
* *If the study involves randomization, describe the randomization procedures and the chances of being assigned to any one group.*
* *If your research involves deception, state the following:* For scientific reasons, this consent form does not contain all of the information about the research question being tested. The researchers will give you more information when your participation in the study is over.
* *If the study involves a survey, inform the participant if the survey is anonymous (e.g. responses cannot be directly/indirectly linked back to the identity of the individual) or confidential.*

**RISKS, DISCOMFORTS, & INCONVENIENCES**

The risks, discomforts, or inconveniences involved with participation in this study may include *[describe risks/discomforts/inconveniences]*.

* *Risk may include psychological, physical, legal, social/reputational, and/or economic/financial harm to participants. In qualitative research, common sources of potential harm include invasion of privacy, stigmatization, or breach of confidentiality.*
* *For each risk/discomfort you list, describe the mechanism(s) you will employ to mitigate those risks/discomforts. All risks identified in the protocol must be addressed in the consent form.*
* *State the following if the study involves risk to privacy or confidentiality:* Please see the ‘PRIVACY & CONFIDENTIALITY’ section below for steps we will take to minimize an invasion of privacy or breach of confidentiality from occurring.
* *Describe access to available support services or procedures to be followed should harm to the participant occur (e.g., participant becomes emotionally distressed during or after an interview, etc.).*
* *If the research involves an interview or survey, inform the participant that they have the right to skip or not answer any question, for any reason. Additionally, inform the participant if the study includes some questions that may seem sensitive or personal in nature.*

**BENEFITS**

The possible benefits you may experience from being in this study include *[describe benefits]*.

***Note****: Compensation or incentives provided for participation is NOT considered a benefit to participants.*

*OR*

There will be no benefit to you from participating in this study. However, we hope the information gained will help *[describe anticipated benefit to society as a whole]*.

**COMPENSATION**

You will not be compensated for being in this study.

*OR*

To compensate for the time, effort, and inconvenience of participating in this study, you will receive *[describe compensation]*. Compensation is considered taxable income.

* *Explain the type of compensation offered (e.g., cash, raffle prizes, gift cards, etc.), the monetary amount of the compensation, and the terms of the compensation (e.g., payment provided after participation is completed, tiered payment approach, what happens if participant withdraws early from the study, etc.).*
* *If total compensation offered is $600 or more, state the following:* Amounts of $600 or more in a calendar year will be reported by UNE to the Internal Revenue Service (IRS) and a form 1099 will be sent to you.

**COSTS**

There are no costs associated with taking part in this study.

*OR*

If you participate in this study, you will need to pay for *[insert description of costs (e.g., parking, child care, travel, clinic or diagnostic fees, etc.)]*.

*Specify if participants will be provided any reimbursement for costs incurred due to study participation (e.g., parking, transportation, etc.) and provide details of the reimbursement process.*

**PRIVACY & CONFIDENTIALITY**

Every effort will be made to keep your research records private and confidential. However, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is required, UNE will take steps allowable by law to protect the privacy of your personal information. In some cases, your information in this study could be reviewed by representatives of the University such as the Office of Research Integrity and/or the Institutional Review Board, research sponsors, or government agencies as necessary.

The results of this study may be shown at meetings or published in journals to inform other professionals. If any papers or talks are given about this research, your name will not be used.

The following additional measures will be taken to protect your privacy and confidentiality: *[Using bullet points, list out the specific mitigation strategies you will employ as part of your study]*

***General Considerations****:*

* *Explain how the participant’s privacy will be protected (e.g., conducting the consent process in a private setting away from others, ensuring that private data are not collected without the participant’s knowledge and consent).*
* *Describe how paper records will be secured and who will have access to them (e.g., storage of paper records in a locked file cabinet in a locked office accessible only by the PI and/or study team).*
* *Indicate how electronic data will be secured and who will have access to them (e.g., through use of encryption, use of a password-protected computer, restricting access to data to the study team only).*
* *If a master list or key is used to retain participant identifiers linked to coded study data, describe what information will be recorded in this document (e.g., participant name and e-mail address linked to a unique study ID number). Specify the master list or key will be stored securely, and separately from the study data. Indicate whether the master list or key will be destroyed (and if it will be destroyed, when this will happen).*

***Specific Considerations for Studies Involving Focus Groups & Interviews***

* *For interviews conducted online, participants should be informed they have the option to not turn on their camera if they choose.*
* *For focus groups, participants should be advised to not repeat anything they learn to others as a means to protect participant confidentiality.*
* *Stripping interviews of all personally identifiable information during the transcription process. Use of a unique pseudonym or study ID number instead of the participant’s name.*
* *For interviews, destroying the audio/video recording at the earliest opportunity during the project (e.g., after all transcripts have been verified for accuracy).*

**USE OF YOUR INFORMATION OR SAMPLES FOR FUTURE RESEARCH**

Your information or samples collected for this study will NOT be used or shared for future research, even if we remove the identifiable information like your name or date of birth.

*OR*

All identifiable information (e.g., your name, date of birth) will be removed from the information or samples collected in this study. After we remove all identifiers, the information or samples may be used for future research or shared with other researchers without your additional informed consent.

**RIGHT TO WITHDRAW FROM THE STUDY**

Your participation in this research study is completely voluntary. You have the right to choose not to participate, or to withdraw your participation at any time without penalty or loss of benefits. You will not be treated differently if you decide to stop taking part in this study.

*Indicate the consequences of a participant’s decision to withdraw from the research (e.g., the study intervention will not be available to the participant), and detail the procedures to be followed for orderly termination of participation by the participant.*

If you choose to leave the study early, data collected until that point will *[remain in the study database and will not be removed,* ***OR*** *be deleted from the study database*]. *If the study involves anonymous data collection, let the participant know that their data cannot be deleted because there is no way to trace the data back to individual participants.*

**RESEARCH RELATED INJURY***[Delete this section for studies that are minimal risk]*

If you are injured or become sick as a result of this study, any emergency treatment will be at your cost. UNE makes no commitment to provide free medical care or money for injuries to participants in this study.

It is important for you to tell the Principal Investigator immediately if you have been injured or become sick because of taking part in this study. They will let you know what you should do.

If you volunteer to participate in the research, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

**DOCUMENTATION OF CONSENT**

You are making a decision whether to participate in this research. Your signature below indicates that you have read this form (or the form was read to you) and that all questions have been answered to your satisfaction. By signing this consent form, you are not waiving any of your legal rights as a research participant. A copy of this consent form will be provided to you.

I agree to participate in this research.

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| Signature of participant or participant’s legally authorized representative |  | Date |

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| Printed name of participant or participant’s legally authorized representative |  | If applicable, a description of the legally authorized representative’s authority to sign for the participant *(e.g., parent, legal guardian, health care agent, etc.)* |

#### Researcher Signature (to be completed at time of informed consent)

I have explained the research to the participant and answered all of their questions. I believe that they understand the information described in this consent form and freely consents to participate.

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| Signature of research team member |  | Date |

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| Printed name of research team member |

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| **Appendix A Instructions** **\*\*Delete this instructional table when you have completed the consent form\*\*** * This appendix contains additional information that may need to be included in your consent form to comply with federal regulations depending on the type of study you are conducting.
* Copy and paste any relevant section(s) from this appendix into Part II of the consent form.
* Delete the contents of Appendix A when you are finished.
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**NEW INFORMATION THAT MAY AFFECT YOUR DECISION TO PARTICIPATE**

*[This section may not apply to social/behavioral/educational studies or studies consisting of a single interaction]*

We will inform you of any significant new findings that become available during the course of the study, such as changes in the risks or benefits resulting from participating in the research or new alternatives to participation that might change your mind about participating. *[Discuss the procedures for informing/updating participants that may affect their decision to participate (e.g., we may ask you to sign a new consent form if the information is provided to you after you have joined the study).]*

**YOUR REMOVAL FROM THE STUDY**

The investigators have the right to stop your participation in this study at any time. This could happen because *[include any circumstance or conditions in which the research team would remove a participant from the study (e.g., noncompliance with research procedures, participant has an unexpected reaction, entire study has been stopped, etc.)]*.

**UNFORSEEABLE RISKS**

The particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or becomes pregnant) that are currently unforeseeable.

**FUTURE USE OF BIOSPECIMENS**

Your biospecimens (even if identifiers are removed) may be used for commercial profit and you *[will or will not]* share in any commercial profit.

**RETURN OF CLINICALLY RELEVANT RESEARCH RESULTS**

During the course of this study the investigators may come across clinically relevant research results, including individual results about you. Should this occur, the investigators *[will or will not]* share this information with you. *If clinically relevant research results will be shared with participants, describe under what conditions this would happen.*

**RESEARCH INVOLVING BIOSPECIMENS**

*State whether the research will (if known) or might include whole genome sequencing (e.g., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).*

**CERTIFICATE OF CONFIDENTIALITY**

To help us protect your information, this research study has a Certificate of Confidentiality from the National Institute of Health (NIH). With this certificate, the research team cannot be forced to provide your name or any identifiable research data or specimens in any federal, state or local proceedings unless you agree that we can share it. However, we still must report information to local authorities if we learn about child abuse or neglect, or intent to harm yourself or others.

Disclosure will be necessary upon request from the Department of Health and Human Services (DHHS) or other federal agencies for audits or program evaluations. *[If you study is not funded by DHHS, delete this statement.]*

This policy does not prevent you from voluntarily releasing information about your own participation in this study.

*If you have obtained a Certificate of Confidentiality from a non-NIH agency (e.g., CDC, FDA, HRSA, SAMHSA, etc.), use the suggested template language from that agency.*

**CLINICAL TRIALS**

*[Use the following language below for NIH-funded clinical trials and other registered trials that do not meet the definition of an FDA applicable clinical trial]*

***Note****: NIH defines a clinical trial as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other controls) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.*

A description of this clinical trial will be available on <https://www.clinicaltrials.gov/>. 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.