

The University of Arizona Consent to Participate in Research

Study Title:

Principal Investigator:

Sponsor:

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

You may or may not benefit as a result of participating in this study. Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious, depending on the nature of the research.

1. Why is this study being done?

2. How many people will take part in this study?

3. What will happen if I take part in this study?

4. How long will I be in the study?

5. Can I stop being in the study?

Your participation is voluntary. You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The University of Arizona. If you are a student or employee at the University of Arizona, your decision will not affect your grades or employment status.

6. What risks, side effects or discomforts can I expect from being in the study?

37 **7. What benefits can I expect from being in the study?**

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40 **8. What other choices do I have if I do not take part in the study?**

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42 You may choose not to participate without penalty or loss of benefits to which you are
43 otherwise entitled.
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46 **9. Will my study-related information be kept confidential?**

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48 Efforts will be made to keep your study-related information confidential. However, there
49 may be circumstances where this information must be released. For example, personal
50 information regarding your participation in this study may be disclosed if required by state
51 law.
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53 Also, your records may be reviewed by the following groups (as applicable to the
54 research):

- 55 • Office for Human Research Protections or other federal, state, or international
 - 56 regulatory agencies
 - 57 • The University of Arizona Institutional Review Board or Office of Responsible
 - 58 Research Practices
 - 59 • The sponsor supporting the study, their agents or study monitors
- 60

61 **10. What are the costs of taking part in this study?**

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65 **11. Will I be paid for taking part in this study?**

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67 By law, payments to subjects may be considered taxable income.
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70 **12. What happens if I am injured because I took part in this study?**

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72 If you suffer an injury from participating in this study, you should seek treatment. The
73 University of Arizona has no funds set aside for the payment of treatment expenses for
74 this study.
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77 **13. What are my rights if I take part in this study?**

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact _____.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Protection Program at 520-626-6721 or orcr.vpr.arizona.edu/irb.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact _____.

Signing the consent form

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

Printed name of subject

Signature of subject

Date and time

AM/PM

Printed name of person authorized to consent for subject
(when applicable)

Signature of person authorized to consent for subject
(when applicable)

Relationship to the subject

Date and time

AM/PM

Investigator/Research Staff

I have explained the research to the participant or the participant's representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or to the participant's representative.

Printed name of person obtaining consent

Signature of person obtaining consent

Date and time

AM/PM

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness

Signature of witness

Date and time

AM/PM

Printed name of witness

Signature of witness

Date and time

AM/PM

