Consent to Participate in Research

Instructions (Delete this section and the left hand column before submitting the consent form in Mentor IRB):

Note to Principal Investigator/Researcher: This template encompasses all of the required and some of the additional elements of informed consent.

* Text that does not apply to your research should be deleted or modified as appropriate
* The text is intended to be instructional rather than declarative
* Be sure to delete all instructive text which is in red (instruction) or blue (insert text) and italicized throughout the document before submitting the document for IRB review

R = required for all consent documents I/A = if applicable, study dependent

Informed consent documents that are 4 pages or longer:

* Are required to begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant understanding the reasons why one might or might not want to participate
* Information included in this section does NOT have to be repeated later in the document
* Do this section after you determine that your informed consent document is 4 pages or longer

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| --- | --- |
|  | **Study Title:** Click here to enter text.  **Name of Researcher (Principal Investigator):** Click here to enter text.  **Faculty Advisory (if applicable):** Click here to enter text.  **Telephone Number/Email Address:** Click here to enter text.  **Funding Organization:** Click here to enter text. |
| I/A | **Key Information**  Study Purpose:  Major Requirements of the Study:  Significant Risks:  Potential Benefits:  Duration of Participation: |
| R | **Introduction**  You are invited to take part in a research study conducted by {Name of PI/Faculty Sponsor, and Student Investigator if applicable} from the department of {blank} at Northern Kentucky University. Before you decide whether or not to participate in the study, you should read this form and ask questions if there is anything that you do not understand. |
| R | **Why are we doing this research?**  In this research study we want to learn more about {describe the nature and purpose of the research in layperson’s language}.  We are asking you and other people with {describe the inclusion criteria met by the potential participants} to be in the research, because {describe the inclusion criteria met by the potential participants if not stated earlier}. |
| R | **Who should be in the research?**  You should be in the research study {describe the inclusion criteria}. |
| I/A | **Who should not be in the research?**  You should not be in the research study if {describe the exclusion criteria}. |
| R | **What will you do in the research?**  If you decide to take part in this study, here is what will happen: {explanation of what will happen to the subject; what type of information will be sought; state what portions, if any, are considered experimental.} |
| R | **How long will you be in this research?**  Participation will take approximately {enter time}. |
| R | **What Other Choices are There?**  {Use words to the following effect} Your participation is completely voluntary; you are free to change your mind at any time and quit the study.  {If study involves survey or interview questions:} You may skip any questions you do not wish to answer. Whatever you decide will in no way {insert appropriate language: penalize you, affect your grade, impact your status as a student} or result in loss of benefits or services to which you are otherwise entitled.  {If payment or course credit is being offered, include the following phrase:} You will still receive full {payment or credit, as applicable} for the study. |
| R | **What are the bad things that can happen from this research?**  {Explain any risks or discomfort - including psychological discomfort - that might reasonably be expected to happen}.  {If identifiable information is collected, then state} There is a risk that your identifiable information could be accidentally disclosed; however, the researchers are taking measures to protect your data. |
| R | **What are the good things that can happen from this research?**  {Describe benefits to the subject, or to others, of this study. If of no direct benefit to the subject, include a sentence to the following effect} Although there will be no direct benefit to you for taking part in this study, the researcher may learn more about {description}. |
| R | **How will information about you be kept private?**  {Describe the way you will maintain the confidentiality of records that identify the subject. Use words to the following effect, if appropriate} The information that you give in the study will be handled confidentially. Your name will not be used in any report. Identifiable research data will be encrypted and password protected.  {If you will be coding the data} Your responses will be assigned a code number. The list connecting your name to this code will be kept in an encrypted and password protected file. Only the researcher will have access to the file. When the study is completed and the data have been analyzed, the list will be destroyed.  {Add statement that study is available at clinicaltrials.gov if it meets the [definition](https://nexus.od.nih.gov/all/2017/10/11/new-video-provides-overview-of-new-nih-policies-on-human-subjects-research-and-clinical-trials/) of a [clinical trial](https://grants.nih.gov/policy/clinical-trials/definition.htm)} A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.clinicaltrials.gov), as required by U.S. Law. This website will not include information that can identify you and will include a summary of the results. You can search this website at any time.    {If you are using an audio or video recording, or photographs in the study, describe if and when such materials will be destroyed} With your permission, I would like to audiotape this interview so that I can make an accurate transcript. Once I have made the transcript, I will erase the recordings. Your name will not be in the transcript or my notes.  {For a focus group} You will not be identified in any report or publication of this study. Even though we will tell all participants in the study that the comments made during the focus group should be kept confidential, it is possible that participants may repeat comments outside the group.  {If the study will be anonymous, use words to the following effect} The information that you give in the study will be anonymous. Your name will not be collected or linked to your answers.  {If it is possible to deduce the participant’s identity through their responses, state the following} Because of the nature of the data, it may be possible to deduce your identity; however, there will be no attempt to do so and your data will be reported in a way that will not identify you.  {If the study is utilizing MTurk} Please note that the data you provide may be collected and used by Amazon as per its privacy agreement.  Additionally, this research is for residents of the United States over the age of 18\*; if you are not a resident of the United States and/or under the age of 18, please do not complete this survey. *\*this assumes that the researcher is seeking subjects 18 years of age and older and haven’t requested a waiver of parental consent.* Amazon could link your worker ID and personal information with your survey responses. Make sure you have read Amazon’s MTurk participant and privacy agreements to understand how your personal information may be used or disclosed.  {If the study involves information that legally must be reported to government agencies, then include the following} Your part in this study is confidential within legal limits. The researchers will protect your privacy unless they are required by law to report information to city, state or federal authorities, or to give information to a court of law. Otherwise, none of the information will identify you by name. All records will be for at least six years and {describe how they are to be maintained}.  {If you would like to keep study data for future analysis} We would like your permission to keep your data for use in future research studies that {describe}.  If you agree, {describe how the data will be used and how confidentiality will be protected}. |
| I/A | **Will you be paid to be in this research study?**  You will receive {$X or/ X credits} for participating in this study. |
| I/A | **Alternatives**  {If applicable, List any alternatives available to the subject for obtaining the same benefit without participating in research – e.g. alternative therapies, in the case of clinical trials, or alternative assignments worth the same academic credit for comparable effort:} |
| I/A | **Commercial profits**  {If applicable use this statement or a similar statement if collecting any biospecimens}Specimens collected from you for this study and/or information derived from your specimens will become the property of the {insert text} or a third party designated by the University. The information/specimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or other compensation from products developed using the information/specimens. |
| I/A | **Will we share the research results with you?**  {If applicable, use this statement or a similar statement if collecting biospecimens or data that may reveal clinically relevant results} You will/will not receive any clinically relevant results discovered about you and/or the general subject population. |
| I/A | **What happens if you are injured from being in this research?**  {If applicable use this statement or a similar statement if the study is greater than minimal risk} {Explain whether any medical or other treatment is available if injury occurs, and who to contact; use words to this effect:} If this study causes you any injury, you should write or call {names} at {phone number}. |
| I/A | **Whole Genome Sequencing**  {If applicable, studies involving whole genome sequencing review and use template language from <https://cdp.cancer.gov/resources/elsi/docs/Model_Consent_Genomic_Sequencing.docx> |
| I/A | **Mandated Reporting**  We are mandated reporters. This means that if we learn or suspect that a child is being abused or neglected, we’re required to report this to the authorities. |
| I/A | **NIH Certificate of Confidentiality**  {If applicable use this statement or a similar statement if the study is NIH funded and collects identifiable, sensitive information OR if the study is not funded and collects identifiable, sensitive information and the study would like to apply for a certificate of confidentiality} To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.  {Use the following language as applicable} The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.  {Language such as the following should be included if researchers intend to make voluntary disclosure about information obtained in the research such as child abuse, or intent to hurt self or others: The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of {list what will be reported, such as child abuse and neglect, or harm to self or others}. |
| R | **Who do you call if you have questions or problems?**  If you have questions about this research, please contact the researcher listed on page 1 of this consent form. You may also contact the faculty member supervising this work: {faculty advisor’s researcher’s name, title, phone number, and email address}.  If you have any questions regarding your rights as a research participant, please contact the Chair of NKU’s IRB, Andrea Lambert South, Ph.D., 859-572-6615 or [irbchair@nku.edu](mailto:irbchair@nku.edu). |
| I/A | **Verifying Consent**  {Use this statement or something similar when requesting a waiver of documentation of informed consent and will be verified electronic consent} By clicking continue, I am consenting to being a participant in this study.  {Use this statement or something similar when requesting a waiver of documentation of informed consent and consent is not being verified electronically} I understand that signature will not be collected in this study to verify consent. Instead, my completion of the study activity/procedures will verify that I have read this document and consent to participating. |
| I/A | **Signatures**  {If applicable use this statement or a similar statement if the study will be collecting documentation (signature) of informed consent} Signing this document means that you understand the information given to you in this form and that you voluntarily agree to participate in the research described above.  {A checklist like this can be used if appropriate}:  I agree to be interviewed.  I agree to have my interview audiotaped.  **Participant**  **\_**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Printed Name of Research Participant  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_  Signature of Research Participant Indicating Consent Date  **Legally Authorized Representative (LAR)**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_  Signature of Legally Authorized Representative (LAR), Date  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Description of the LAR’s authority must be provided  **Study Staff**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_  Signature of Individual Obtaining Consent Date  Please sign both consent forms, keeping one for yourself OR  A copy of this document will be made for you. |