**The University of Akron**

**Institutional Review Board**

**Sample Informed Consent Document**

The following sample informed consent document includes instructions to the person writing the document, followed by sample language that may be used in the actual document. *{Instructions to the person preparing the form are always written in script and enclosed in brackets, like this.}* Sample language that *may* be used in the actual document is always written in standard typeface, like this.

The consent form *must*be printed on the principal investigator’s University department letterhead. If the investigator is a student, the Faculty Advisor’s department letterhead should be used. It is recommended that the document include section headings in bold type. For on-line consents, letterhead is not required.

**Required Elements for Consent Document**

**Title of Study:** {The title on the consent form must match the title on the application except in cases where revealing the true purpose of the study would compromise the results. In those cases, the rationale for the variance must be clearly explained in the IRB application.}

**Introduction:** {Informs participant that this is a research project and identifies who is conducting the research.}

You are invited to participate in a research project being conducted by {name}, a {faculty member, student, etc.} in the Department of {dept. name}, at The University of Akron.

**Purpose:** {Provide a statement of the purpose of the study and an estimate of how many persons are participating in the study.}

**Procedures:** {Describe what the participants will be asked to do for the study. Include all procedures, including number, frequency and duration. Differentiate between procedures that are for research and those that are standard, i.e., teaching methods, assignments, etc. Describe any other data to be collected such as personal records, written material, teacher comments. Specify any post-study follow-up.}

**Exclusion:** {Only include if applicable. Clearly list criteria that would prevent an individual from participating or make someone ineligible to participate}

**Risks and Discomforts:** {For each procedure/activity that is part of the research, describe the immediate and long range discomforts/risks (physical, psychological, social, legal, and economic) and their consequences. Explain safeguards or precautions that will be taken to reduce the occurrence of adverse effects. Explain what treatment or assistance will be available if an adverse effect occurs. For example, in studies in which subjects are asked to discuss emotionally sensitive topics, the IRB requests that either an individual be present who can provide counseling assistance, or referral information be provided to subjects. If there are no known risks, include a statement to that effect.}

**Benefits:** {Only include one of the following choices. This statement should describe reasonable benefits to the participants as a result of participation in the research. If you are evaluating a program or intervention, do not describe the benefits of participation that would have occurred anyway. If the individual participant will receive NO DIRECT BENEFIT, this must be explicitly stated. Payment for participation is NOT considered a benefit of the research.}

The benefits to you for participating in this study may be \_\_\_\_\_\_\_\_\_. However, you may receive no benefit from participating in this study.

OR

You will receive no direct benefit from your participation in this study, but your participation may help us better understand \_\_\_\_\_\_\_\_\_.

**Alternatives:** {Provide a statement describing appropriate alternative procedures or courses of action, if any, which might be substitutes for participating in the research. If the only alternative is simply to not participate in the study, you do not need to include this section.}

**Payments to Participants:** {Only include if financial reimbursements or recruitment incentives are to be given to participants. Specify dollar amount and form of payment, i.e. cash, gift certificate, item. Explain if and how the payment will be prorated if the participant withdraws. Also indicate when payment will be received, eg, at end of session, one week later, after each intervention, etc.}

**Right to refuse or withdraw:** {Provide a statement explaining that participation is voluntary and that refusal to participate or withdraw from the study at any time will involve no penalty or loss of benefits to which they are otherwise entitled. For most survey research, simply stating that participation is voluntary is sufficient. For projects involving students, this should include a statement that failure to participate will in no way affect their grade. For projects involving prisoners, include a statement that participation, or non-participation, will in no way influence their case. Include information about when a participant may withdraw (e.g. before de-identification of the data) Sample language is provided below for this last point}.

If you decide to withdraw from the study after de-identification occurs, we will not have any way of knowing which data points are yours. Therefore, we will not be able to remove your data from the study and it may be shared as described above. **\*NOTE: If data are collected already de-identified, change the language to indicate it will not be possible to withdraw after completing the intervention.**

**Anonymous and Confidential Data Collection:** *{Indicate whether data collection will be (a) anonymous or (b) confidential.*

*The term anonymous is used when the investigator collects no identifying information about subjects, and thus, an individual data sheet cannot be connected with a specific subject (by the investigator or anyone else) once the data is collected. Audio or video recordings, by their very nature, are identifiable and cannot be anonymous*.

Confidential, in contrast, refers to data which is collected in a way that it can be linked to an individual subject. For example, assigning subjects numbers, but then keeping a "key" that links the numbers to identifying information, is a procedure one might use in order to preserve confidentiality. Not identifying subjects by name or any other identifying information in reports and presentations also is a measure taken to preserve confidentiality. If individual subject data are used as illustrative examples, you must assure subjects that this will be done in a way that does not allow identification of the participant. Care must be taken to not only protect subjects' names, but also other details about them or their experiences that would allow them to be identified. Occasionally, it is important to the research to identify an individual who participated, or subjects themselves may wish to have their contribution attributed to them. This is most likely to occur in some qualitative studies, and is acceptable as long as specific written permission is granted by the subject.

The following sample statements are provided – modify as needed:

*For Anonymous data*- No identifying information will be included in the data you provide. Your signed consent form will be kept separate from your data, and it is unlikely anybody be able to link your responses to you. However, whenever demographic data are collected, there is always the possibility that your responses could be linked back to you. We think this possibility is very slight.

OR – No identifying information will be collected, and your anonymity is further protected by not asking you to sign and return the informed consent form. However, whenever demographic data are collected, there is always the possibility that your responses could be linked back to you. We think this possibility is very slight.

*For Confidential data* - Any identifying information collected will be kept in a secure location and only the researchers will have access to the data. Participants will not be individually identified in any publication or presentation of the research results. Only aggregate data will be used. Your signed consent form will be kept separate from your data, and nobody will be able to link your responses to you.

**Confidentiality of records:** *{*This section should describe the extent to which confidentiality of records will be maintained, i.e., coding of data, any limitations to confidentiality, disposition of data at the conclusion of the study. Address all forms of data to be collected – written, audio, video. Confidentiality procedures explained here must be consistent with those stated in the IRB application.]

The following sample statements are provided – modify as needed:

We will protect your information and make every effort to keep your personal information private, but we cannot promise complete confidentiality. No information which could identify you will be shared in publications about this study.

Your personal information may be shared outside the research study if required by law. We also may need to share your research records with other groups for quality assurance or data analysis. These groups include the University of Akron’s Institutional Review Board or its designees, and state or federal agencies who may need to access the research records (as allowed by law).

**Future research/Sharing of data:** *{*This section should describe the extent to which data may be shared outside of this study or for future research.]

The following sample statements are provided – modify as needed:

Information collected for this study may be used for other research studies or shared with other researchers who are conducting their own research studies. This may include sharing with researchers outside the University of Akron [and sharing with private companies]. It may also include making the information available in public and private databases of research data so that other researchers can use the information to answer research questions.

If we share your information in this way, we will remove information that could identify you, such as your name and contact information, before any information is shared. Since identifying information will be removed, we will not ask for your additional consent for this sharing. Any research data collected from you, other than your personally identifiable information, could be included in such sharing. Even though the data will be de-identified prior to sharing with others, there may be a risk of you being identified. Anybody in the world can have access to such data. If you tell others you participated in the study, this may increase the chance someone could identify you from the data.

We do not know how likely it is that your identity could become re-connected with information shared through public databases (e.g. open access). We believe there is low risk that de-identified study data could be used to re-identify you. However, it may be possible that in the future, it will be more easy to identify a person from such de-identified data.

**Who to contact with questions:** {Provide an explanation of whom to contact for answers to pertinent questions about the research. If the investigator is a student, also include the advisor’s name and number. Use of home numbers is not advised. Also include the IRB approval and contact information for questions regarding the rights of research participants.}

If you have any questions about this study, you may call {investigator} at {campus number} or {advisor’s name, if investigator is a student} at {phone number}.This project has been reviewed and approved by The University of Akron Institutional Review Board.If you have any questions about your rights as a research participant, you may call the IRB at {phone number}.

**Acceptance & signature:** {Provide a statement in which the participant affirms his/her understanding and willingness to be involved in the study. This will vary depending on whether or not the IRB has approved a waiver of signed consent.}

Use the following statement and signature line when a signed consent will be returned to the investigator:

I have read the information provided above and all of my questions have been answered. I voluntarily agree to participate in this study. I will receive a copy of this consent form for my information.

**Participant’s Printed Name:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Participant’s Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Date**: \_\_\_\_\_\_\_\_\_\_\_\_

**Printed Name of Person Obtaining Consent:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature of Person Obtaining Consent**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Date**: \_\_\_\_\_\_\_\_\_\_\_\_\_

**The researcher may request, and the IRB may grant, a waiver of signed consent if one of the following conditions is true and is stated in the application:**

1. **The only record linking the subject to the research would be the consent form, and the principal risk is potential harm from breach of confidentiality.**
2. **The research presents no more than minimal risk and involves no procedures for which written consent is normally required outside of the research context.**

Use the following statement when a waiver of signed consent has been approved:

I have read the information provided above and all of my questions have been answered. I voluntarily agree to participate in this study. My completion and return of this {survey, instrument, questionnaire} will serve as my consent. I have been given a copy of this consent form for future reference.

Use the following statement for on-line consents:

I have read the information provided and all of my questions have been answered. I voluntarily agree to participate in this study. My completion and return of this {survey, instrument, questionnaire} will serve as my consent. I may print a copy of this consent statement for future reference.

**[The signed consent form should be placed in the investigator’s study file. Identifying data should be kept in a separate file and linked with a code through a link list. A copy of the consent form must be given to each participant for their information (it may be unsigned.) }**

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**Research Involving Minors (under 18) –** see the Guidelines for Parental Consent and Child Assent for Children under 18.

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**Additional Clauses for Special Circumstances – use only if applicable to your study**

**Abuse:** {Include the following statement if the nature of the research study makes it likely for participants to reveal reportable information.}

The investigator has ethical and legal obligations to report suspected child abuse or neglect and to prevent you from carrying out any threats to do serious harm to yourself or others. If keeping information obtained in this study private would immediately put you or someone else in danger, the investigators would release that information to protect you or another person.

**Audio and Video Recording:** {If you wish to recording subjects, please include a request to record explaining the type (e.g. videorecording in the classroom, audio recording, single or group interviews, etc.), and the disposition of the recording (s) when the study is complete. If the recordings will be used for any other purpose, clearly state the who, where, and why of the other use; if there is no other use of the recording, simply stating that it will be erased when the study is complete is sufficient.}

**Certificate of Confidentiality:** {Use the following paragraphs ONLY if a Certificate of Confidentiality is being requested through the National Institutes of Health. This Certificate places legal burdens on an investigator and is not issued lightly. Most studies do not need a Certificate of Confidentiality. Please contact the IRB at {phone number} is you are unsure of the need for this.}

To further protect your privacy, the investigators have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this certificate, the investigators may not disclose information (for example by court order or subpoena) that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings\*. Disclosure may be necessary, however, upon request of DHHS for audit or program evaluation purposes.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

\*The researchers should include language such as the following if they intend to make voluntary disclosure about things such as child abuse, intent to hurt self or others, or other voluntary disclosures.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances. {The researchers should state here the conditions under which voluntary disclosure would be made. If no voluntary disclosures will be made, the researchers should so state.}