# Parental Informed Consent Document Instructions:

If your study is classified as nonexempt, providing and documenting informed consent is required unless you have been granted a waiver or alteration of informed consent or documentation of consent. If minors are included in your study, you will need to provide a consent form for parents and an age-appropriate assent form for minors. This form is a guide for creating a parent informed consent document.

One of the easiest ways to do this is to provide participants with a written document, but there are other options available to you:

* Electronic form and signature capture
* Preamble to a survey with an overt action that signifies consent (e.g., clicking on a link)
* Others – check with your advisor or the ACIRB if you have questions

The following information needs to be included in your method of informed consent, but not necessarily in this order. A template is included at the end of this document that you may customize for your use.

# Study Introduction and Details

* Study title
* Name of investigator and contact information
* Invitation to participate, purpose of research, and anticipated benefits
	+ Specify the criteria for inclusion – Why are they being asked to participate?
	+ Describe the study purpose and benefits – What do you wish to learn?

# Participation Details

* What data will be collected and methods used (e.g., survey, interviews, focus groups, etc.)
* Where and when data collection will take place (describe the location – e.g., online, on campus, at an office, and provide approximate dates)
* How long data collection will take (e.g., minutes, hours, months)

# Data Use and Risks

* How the data will be used (e.g., publications, conferences, public talks)
* Who will have access to the research data (e.g., research team members, investigator)
* Possible risks and protections in place (describe possible risks and what to do if risks occur – list of resources or contacts)
	+ University of Oregon – [Examples of risks](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/examples-potential-risks-subjects)
	+ Columbia University – [Potential risks](https://www.tc.columbia.edu/institutional-review-board/how-to-submit/guides--resources/understanding-potential-risks-for-human-subjects-research/)
	+ UC Davis – [List of common risk types](https://research.ucdavis.edu/policiescompliance/irb-admin/researchers/project-guidance/risks-and-benefits/)

# Confidentiality Measures and Data Storage

* What identifying information will be collected and why
* Where and how data will be securely stored
* What form will data be stored and for how long

# Research Incentives or Benefits

* What opportunities are available to participants and assurance that if a participant withdraws from the study, they should still receive the compensation or reimbursement of costs incurred

# Participant Rights Details

* Voluntary participation
	+ Example text – Your participation in this research is strictly voluntary.
* Right to withdraw
	+ Example text – You may withdraw from the project, without penalty, by…
* Access to findings (if applicable)
	+ How will they be able to access the results?
* Clarify understandings
	+ If they have any questions, who do they contact? Include details.

# Completion of Ethical Reviews

* State if any ethical review processes have been completed and contact details for this review
	+ It is helpful to include a statement that this study was reviewed by the ACIRB and include contact details:

Allen College Institutional Review Board (ACIRB) – ACIRB@allencollege.edu

Or

Brenda C. Barnes, PhD, MLS(ASCP)SBB Administrator, Allen College Institutional Review Board
Allen College – UnityPoint Health
1825 Logan Ave.
Waterloo, IA  50703
Brenda.barnes@allencollege.edu
(319) 226-2082 office
(319) 226-2508 fax

# Final Instructions to Participate

* How to access survey or who to contact to participate
* How to provide consent documentation (e.g., clicking this link indicates your consent, completing a survey or exam, verbally consenting, etc.)
* Inform participants to keep letter of information as a record (if a written form is provided; otherwise, tell them who to contact if they want more information and include details)

# Practical Tips:

* Do not overstate benefits
* Use, simple, jargon-free language
	+ It may be helpful to measure the readability of your document at readable.com, [readability.com](file:///%5C%5Cihs.org%5CALO%5CALO2_USERS%5CSHARED%5CAllen%20College%5CCommittee%5CInstitutional%20Review%20Board%5CBrenda%20To-Do%5Creadibility.com), or through your word processing program
* State participant expectations clearly
* Be specific about research incentives (if used)
* Explain how consent is documented

# Template Instructions:

You may use the template on the following pages to create or written consent form or use it as a guide for information that must be included in the informed consent process. The red text provides instructions and/or example text. Delete all the text in red after you have customized the information for your use as well as the instructions on these first two pages.

**PARENTAL INFORMED CONSENT DOCUMENT**

**Title of Project:**

**Graduate student:** List project coordinator; others may be included at the PC’s discretion.

This is a research project that your child is invited to take part in. Please take your time in deciding if you will grant permission for him or her to participate. Please feel free to ask questions at any time.

# Introduction

# The purpose of this project is to [Give a general description of the project and the kind of information that it is hoped will be gained using lay person’s terminology. For example, learn more about community attitudes towards a new recreation center; learn if attending preschool gives children an advantage when they start kindergarten, etc.].

Your child is being invited to participate in this project because [Describe the reason they are being asked to participate, any inclusion criteria, **in lay person’s terms** (e.g.,an athlete who is not taking medication, a student in the 5th grade, a 4-H member, etc.).]. If applicable, add: He or she should not participate if [Describe any exclusion criteria, also in lay person’s terms.]

This project is funded by [name of funding agency]. (**Optional)**

# Description of Procedures

If you allow your child to participate, your child will be asked to [Explain **ALL** procedures that subjects will be asked to take part in and the information subjects will be asked to provide using **lay person’s terminology** (e.g., your child will be asked to complete a survey about his or her attitudes towards alcohol use; to walk on a treadmill for 15 minutes and then his or her heart rate and blood pressure will be checked; your child will be asked to visit our lab once per week for the next four weeks to provide 2 teaspoons of blood; etc.)].

Your child’s participation will last for [Include the total expected duration of subjects’ participation, including the estimated amount of time needed to complete each component of the research (when relevant) and the number of visits/contacts needed.].

* The description should be clear and easy to follow. The use of bullet points, section headings, numbered steps, etc., is encouraged if it helps with readability.
* For surveys, interviews, focus groups, include a description of the types/nature of questions subjects will be asked or the topics to be discussed.
* If participation will be video or audio recorded, this must be stated.
* Include the number of visits or contacts for research that involve contact at multiple time points.

**Note:** The procedures and duration can be combined if desired (e.g., your child will be asked to complete a survey about his or her attitudes toward alcohol use that should take about 20 minutes; your child will be asked to visit our lab once per week for the next four weeks—each visit should last about one hour; your child’s visit to our facility will take about 45 minutes and he or she will be asked to complete an exercise history questionnaire and walk on a treadmill for 20 minutes).

# Risks or Discomforts

While participating in this project your child may experience the following risks or discomforts: [List any and all physical, emotional, psychological, legal, pain, inconvenience, and privacy issues. If there are no known risks/discomforts, state that there are no foreseeable risks or discomforts at this time from participating in this project.].

# Benefits

If you allow your child to participate in this project, there [may be no/will be no—select the appropriate phrase]direct benefit to you or your child. It is hoped that the information gained in this project will benefit society by [Describe how the information gained in this project will help society, advance knowledge, etc.].

# Costs and Compensation

You and your child [will/will not] have any costs from participating in this project. [If there will be costs, state specifically what they will be.]Your child [will/will not] be compensated for participating in this project. If participants will be compensated in any amount, add: You or your child will need to complete a form to receive payment. Please know that payments may be subject to tax withholding requirements, which vary depending upon whether you are a legal resident of the U.S. or another country. If required, taxes will be withheld from the payment that is received.

**If the payment is $100 or greater, also include the following language**: Your child’s social security number (SSN) and address will be required on the form in order for us to provide payment.

**Optional—can be used to explain why the information is needed**: This information allows Allen College to fulfill government reporting requirements. Confidentiality measures are in place to keep this information secure. You and your child may forego receipt of payment(s) and continue in the research project if you do not wish to provide your social security number and address. Information regarding documentation required for participant compensation may be obtained from the Allen College IRB Office.

If a person is to receive money or another token of appreciation for their participation, explain when it will be given and any conditions of full or partial payment (e.g., If your child decides to withdraw from the project, he or she will be compensated $5 for each visit.). Completion of all project procedures cannot be required to receive compensation—it is considered coercive to make completion of the entire project the basis for compensation.

**If course credit or extra credit will be given to children for participating, please specify the amount of credit. You must also describe alternative methods for earning extra credit besides participating in the research (e.g., writing a research paper, participating in other research projects).**

**Alternatives to Participation** **Omit if not applicable.**

When applicable, list the alternative treatments/therapies available to the child.

# When course credit is offered to children for participating in the research, describe the availability of non-research alternative ways students can earn the same amount of credit in this section or in the “Costs and Compensation” section above.

# Participant Rights

Your child’s participation in this project is completely voluntary. You can choose not to give consent or you can withdraw consent at any time without any penalties or negative consequences. Your child may also choose not to participate or withdraw from the project at any time without any penalties or negative consequences. If the project involves a survey, interview, focus group, or other similar methods, add: Your child can skip any questions that he or she does not wish to answer.

Where applicable, add examples. Try to anticipate concerns that parents or children may have when choosing whether or not to participate. For example, parents should be informed that whether or not their child takes part in a project will have no impact on their experiences or services received at school, medical care, in a given program, etc.

If applicable, list any foreseeable circumstances and/or reasons that the subject’s participation may be terminated.

If you have any questions *about the rights of research subjects or research-related injury*, please contact the IRB Administrator, (319) 226-2082, or ACIRB@allencollege.edu.

# Confidentiality

Records identifying your child will be kept confidential to the extent permitted by applicable laws and regulations and will not be made publicly available. However, federal government regulatory agencies[list all other applicable groups (e.g., NIH, the sponsor)], and the Institutional Review Board (a committee that reviews and approves human subject research studies) may inspect and/or copy project records for quality assurance and data analysis. These records may contain private information. **If the project is regulated by the FDA, a statement that the FDA may inspect or copy records *must* be included.**

To ensure your child’s confidentiality to the extent permitted by law, the following measures will be taken: [e.g., describe the use of any coding systems, whether identifying information will be collected or retained, etc. If identifiers will be kept with the data, this must be also stated. Also provide specific details of how data and any identifiers will be kept confidential (e.g., locked filing cabinet, password protected computer files, how access will be controlled, etc.).

Describe the extent to which participants’ identities can or will be kept confidential when results of the project are disseminated. If confidentiality cannot or will not be maintained, participants should be informed of this.]

# Questions

You and your child are encouraged to ask questions at any time during this project. For further information ***about the project,*** contact [project coordinator’s name and contact information; ***for a student project*,** also list the supervising faculty member’s name and contact information and Allen College’s IRB contact information. Contact information should include mailing address, phone number(s) and email addresses].

# Consent and Authorization Provisions

Your signature indicates that you voluntarily agree to allow your child to participate in this project, that the project has been explained to you, that you have been given the time to read the document, and that your questions have been satisfactorily answered. You will receive a copy of the written informed consent prior to your child’s participation in the project.

The regulations require that the informed consent document shall be given to the person signing the form.

**Child’s Name** (printed)

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

**Printed Name** of Parent/Guardian or Legally Authorized Representative

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

**Signature of** Parent/Guardian or Legally Authorized Representative Date

[NOTE THAT ONE COPY OF THE ENTIRE CONSENT DOCUMENT (NOT JUST THE AGREEMENT STATEMENT) MUST BE RETURNED TO THE PI AND ANOTHER PROVIDED TO THE PARTICIPANT. SIGNED CONSENT FORMS MUST BE MAINTAINED FOR INSPECTION FOR AT LEAST 3 YEARS]

Additional note: Readability level is an important factor to consider when developing documents such as an informed consent. If a document is written at a level that is too high, it is likely that the reader may not fully comprehend the information presented in the document. The IRB members will be concerned with readability level because it directly impacts how well informed a potential participate will be. A good (free) website to use to check your readability level is at [readable.com](https://readable.com/), [readability.com](file:///%5C%5Cihs.org%5CALO%5CALO2_USERS%5CSHARED%5CAllen%20College%5CCommittee%5CInstitutional%20Review%20Board%5CBrenda%20To-Do%5Creadibility.com), or through your word processing program. Please aim for an Average Grade Level of no higher than 8.