# Participant 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.

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.

# ALLEN COLLEGE

**HUMAN PARTICIPANTS REVIEW**

**INFORMED CONSENT**

# (Sample for Adult Participants – Use Second Person Language Except for Agreement Statement)

Project Title: [as it appears on the IRB application]

Name of Investigator(s): [include name and contact information]

**Invitation to Participate**: You must provide a formal invitation to take part in the research project. For example: “You are invited to participate in a project conducted through Allen College. The College requires that you give your signed agreement to participate in this project. The following information is provided to help you made an informed decision about whether or not to participate”. You should specify the criteria for inclusion so potential participants know why they are being asked to participate.

**Nature and Purpose**: State clearly and accurately what the study/project is designed to discover or establish. What do you wish to learn from this study?

**Explanation of Procedures**: Describe all procedures to be followed, including their purpose(s), duration, frequency, use of any audio or video recording, what will happen to the data/information at the end of the study/project. Include enough detail that the participant has a reasonable idea of what he/she will be doing and what he/she will be asked about. State any anticipated circumstances where the participant’s participation may end without regard to the participant’s consent.

**Discomfort and Risks**: Describe any physical, psychological, social, legal, and/or economic risk(s) or cost(s) resulting from the project. If there are no more than minimal risks--discomfort, burden, inconvenience--this should be so stated. This may be stated in one of several ways: Risks to participation are minimal. Risks to participation are similar to those experienced in day-to-day life. There are no foreseeable risks to participation.

**Benefits and Compensation**: Describe any direct benefit(s) that may result from the study/project. Benefits would include improved physical or mental health (e.g., from treatment), improved skills, etc. Compensation is distinct from benefit and would include cash, gifts, or academic credit provided for the person’s time or travel expenses. If the individual participant will receive no direct benefit, this should be stated. If applicable, describe how voluntary or involuntary withdrawal or termination affects benefits. Note that compensation should be equivalent across participant groups and cannot be used to coerce participation. That is, if compensation for time is provided, then a portion of the compensation must be provided (pro-rated) even if the person terminates their involvement prior to completing the study.

**Confidentiality**: State the way the participant’s confidentiality will be maintained: persons or organizations to whom information from the study/project will be furnished (including for student presentations), nature of the information furnished, purpose of the disclosure. For example: “Information obtained during this study/project that could be used to identify you will be kept confidential. The summarized findings with no identifying information may be published in an academic journal or presented at a scholarly conference”.

**Right to Refuse or Withdraw**: Provide information about the voluntary nature of participation and the ability of the participant to stop at any time without penalty. For example: “Your participation is completely voluntary. You are free to withdraw from participation at any time or to choose not to participate at all, and by doing so, you will not be penalized or lose benefits to which you are otherwise entitled.”

**Questions**: Participants should be able to seek additional information about the project. For example: “If you have questions about the study/project you may contact or desire information in the future regarding your participation or the study generally, you can contact (investigator) at (319) ===-==== or (if appropriate) the project investigator’s faculty advisor \_\_\_\_\_\_\_\_\_\_\_\_\_ at Allen College at (319) ===-====. You may also contact the Allen College IRB Chair (ACIRB@allencollege.edu), for answers to questions about rights of research participants and the participant review process.”

**Agreement**: Include the following statement:

I am fully aware of the nature and extent of my participation in this project as stated above and the possible risks arising from it. I hereby agree to participate in this project. I acknowledge that I have received a copy of this consent statement. I am 18 years of age or older.

If the participant is unable to make a decision regarding participation, a power of attorney may sign this form. Documentation must be provided to the investigator to prove the signee is an authorized legal representative.

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

(Signature of participant) (Date)

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

(Printed name of participant)

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

(Signature of investigator) (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 THREE 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.