# Information to Participants Document Instructions:

If your study is classified as exempt or you are completing an EBP/QI project, documenting informed consent (i.e., collecting a signature) is not required, but potential participants in your study or project still need to receive information to decide if they want to participate. 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
* Email to potential participants
* Preamble to a survey
* Included as part of a presentation slide set
* Verbally (as part of a presentation)
* Others – check with your advisor or the ACIRB if you have questions

If you are using a method other than a written form, you need to include the following information in your method of informing potential participants:

# Study or Project Introduction and Details

* Study title
* Name of investigator and contact information
* Invitation to participate, purpose of research or project, and anticipated benefits
	+ Specify the criteria for inclusion – Why are they being asked to participate?
	+ Describe the study or project 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 or project, they should still receive the compensation or reimbursement of costs incurred

# Participant Rights Details

* Voluntary participation
	+ Example text – Your participation in this research (or project) 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 a written participant information document or use it as a guide for information that must be included in the participant information document. 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 – UNITYPOINT HEALTH**

**PARTICIPANT INFORMATION DOCUMENT**

# Title of Project:

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

This form describes a student project. It has information to help you decide whether or not you wish to participate. This project includes only people who choose to take part—your participation is completely voluntary. Please discuss any questions you have about the project or about this form with the project staff before deciding to participate. **Please retain this copy for your records**.

# 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. Do not use scientific jargon. If the project is such that subjects must be deceived about the true purpose, explain as much as possible without jeopardizing the research.].

You are 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 adult runner who is not taking medication, a student in a learning community, a member of the Red Cross, etc.).]. If applicable, add: You should not participate if [Describe any exclusion criteria (e.g., under age 18, have certain health conditions, etc.).].

# Description of Procedures

If you agree to participate, you 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., you will be asked to complete a survey about your attitudes towards alcohol use; you will be asked to walk on a treadmill for 15 minutes and then your heart rate and blood pressure will be checked; you will be asked to visit our lab once per week for the next four weeks to provide 2 teaspoons of blood; etc.).]. Your 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 participants will be recorded by audio or video, this must be stated.

# Risks or Discomforts

While participating in this project you may experience the following risks or discomforts: [List any and all physical, emotional, psychological, legal, pain, inconvenience, and privacy issues. Risks may include such things as embarrassment from answering sensitive questions during an interview, discomfort from a blood drawing procedure, skin irritation from application of sensors, implications from a breach of confidentiality, etc. If there are no known risks/discomforts, state that.].

# Participant Rights

Participating in this project is completely voluntary. You may choose not to take part in the project or to stop participating at any time, for any reason, without penalty or negative consequences. For studies involving surveys, interviews, focus groups, or similar methods, add: You can skip any questions that you do not wish to answer.

In this section, try to anticipate concerns participants may have when choosing whether or not to participate, particularly if there are hierarchical relationships between the investigator and subjects. For example, Allen College students may be concerned about negative repercussions related to their position as a student (i.e., grades, future letters of recommendation, assistantships, etc.) if the investigator is a faculty member. Employees may be concerned about negative effects on their employment based on their choice to participate or not. These concerns can be addressed in this section by including statements that directly relate to these issues (e.g., “Your choice of whether or not to participate will have no impact on you as a student/employee in any way.”).

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

# Confidentiality

Records identifying participants 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 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 (in all formats) 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 clearly informed of this.]

# Ethical Review

This study was reviewed by the Allen College Institutional Review Board.

# Questions

You 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].

You may also report a concern about a study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

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
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**You may keep this copy for your records.**