INFORMED CONSENT FORM

Title of Study: [Title of study]

Investigators: [List principal investigator(s); others may be included at the PI's discretion.]

- *Consider naming only key senior personnel to avoid the document becoming repeatedly outdated with changes in staff.*

Information in this document MUST be sufficiently detailed, organized, and presented in a manner that facilitates comprehension.

Invitation to be Part of a Research Study

You are invited to participate in a research study. This form has information to help you decide whether or not you wish to participate—please review it carefully. Research studies include only people who choose to take part—your participation is completely voluntary and you can stop at any time.

Please ask the project staff any questions you have about the study or about this form before deciding to participate.

If your consent form will be longer than four pages, this section must ALSO include a concise and focused presentation of the key information most likely to help your prospective participants understand the reasons they may or may not want to participate. This information MUST be organized and presented in a manner that facilitates understanding. This "concise summary" is a new section that is required by the 2018 Common Rule (Human Subjects Regulations).

Introduction and Purpose of the Study

The purpose of this study is to [Explain the purpose of the study using **layperson's terminology].**

- *Do not use scientific jargon.*
- *If subjects must be deceived about the true purpose, explain as much as possible without jeopardizing the research.*
- *If the study involves the use of **an investigational drug or medical device,** the purpose of the study should also clarify that **"investigational" means that the drug or device is not approved by the Food and Drug Administration]**.*

This study is funded by [name of funding agency]. **Omit if not applicable.**

Eligibility to Participate

You are eligible to participate in this study if [list the inclusion criteria **in layperson's terms**].

You should not participate if [Describe key exclusion criteria].

When applicable, also add: To determine if you are eligible, we will [Describe screening process and procedures].

- *The "Eligibility to Participate" section is optional, unless the inclusion/exclusion criteria relate to subject safety (i.e. avoiding enrollment of those for whom participation may be risky or unsafe) or important as a measure to prevent unintentional enrollment of vulnerable subjects (such as those under 18).*
- *Be sure to inform people if screening procedures may result in participants being excluded.*

Description of Study Procedures

If you agree to participate, you will be asked to [Explain **ALL** procedures that subjects will be asked to take part in during the research].

→ *Use **layperson's terminology; avoid scientific or research jargon.***

→ *Avoid using wording copied/pasted directly from the IRB application or grant proposals. Such wording is typically complex or technical, and not appropriate to explain the study to participants.*

→ *The description should be clear and easy to follow. The use of bullet points, tables, section headings, numbered steps, etc., is encouraged if it helps with readability.*

→ *Include procedures for assessing eligibility/screening, if applicable. Also, inform participants that they may not be selected to participate based on the results from the screening/eligibility assessment.*

→ *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 or their actions will be recorded (audio, video, screen capture, etc.) this must be stated.*

→ *For eligible exempt research, if participants will be deceived regarding the nature or purposes of the research, include a statement such as*

- *You will be unaware of or misled regarding the nature or purposes of the research.*

→ *If blood will be drawn, specify how and from where (from a vein in your arm, from a finger-stick, etc.), the number of times blood will be drawn, and how much blood will be drawn each time and in total (in common measurement terms, such as teaspoons or tablespoons).*

→ *Including photographs of equipment to be used or other visual aids to help promote understanding is encouraged.*

→ *If the study includes any experimental devices, drugs, or other types of experimental treatments/interventions, the consent document should specify which are experimental and which are not.*

→ *If your research involves obtaining biospecimens, participants must be informed if the research will or might include whole genome sequencing. They must also be informed of what whole genome sequencing is and what it means for them, using layperson's terminology.*

Expected Time or Duration of Participation:

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 explanation must accurately and clearly disclose the anticipated time commitment. In general, it is better to slightly over-estimate time commitment**.** If duration will vary, provide estimated time in ranges (e.g., *Interviews will last 2 – 3 hours, depending on how much information you wish to share.*).

→ The procedures and duration sections can be combined if desired (e.g., *You will be asked to complete a survey about your attitudes toward alcohol use that should take about 20 minutes; You will be asked to visit our lab once per week for the next four weeks—each visit should last about one hour; Your visit to our facility will take about 45 minutes and you will be asked to complete an exercise history questionnaire and walk on a treadmill for 20 minutes*).

Risks or Discomforts

While participating in this study you may experience the following risks or discomforts: [List all reasonably foreseeable physical, informational, emotional, psychological, legal, pain, inconvenience, and privacy concerns. Side effects of any drugs, supplements or other items must be noted.]

→ *Risks or discomforts vary greatly by study procedures, and include, but are not limited to such things as:*
- *embarrassment or emotional discomfort from answering sensitive questions during a survey or interview, from being video or audio recorded during study tasks, etc.*
- *harm from a loss of confidentiality,*
- *motion sickness/simulator sickness,*
- *muscle or joint pain/soreness from exercise;*
- *pain, bruising, light-headedness and possible infection from a blood draw,*
- *side effects from drugs or dietary supplements,*
- *allergic or other reactions caused by stimuli or devices (e.g., headaches, seizures, etc.)*
- *skin irritation from application of sensors or wearing activity trackers (e.g., Fitbits, etc.).*

→ *Risks or discomforts should be clearly outlined, **using layperson's terminology**.*

→ *It may be helpful to distinguish risks by expected frequency of occurrence (e.g., those that are likely, those that may occur but are less likely, etc.) and severity (mild, moderate, etc.).*

→ *When applicable, include any measures to mitigate the risk/discomfort.*

→ *If there are no foreseeable risks/discomforts, please inform participants accordingly.*

Consider adding:

There may be risks or discomforts that are currently unforeseeable at this time. We will tell you about any significant new information we learn that may relate to your willingness to continue participating in this study.

When applicable, also add: If you are or become pregnant during this study, there may be risks to the embryo or fetus that are currently unforeseeable.

Benefits to You and to Others

It is hoped that the information gained in this study will benefit society by [Describe how the information gained in this study will help society, advance knowledge, etc.].

You [are not expected to directly benefit from participation in the study] OR [describe the expected ways participants may directly benefit from taking part].

- → *Participants often do not directly benefit from participation in research.*
- → *If there are reasonably foreseeable direct benefits to participants, the **benefits may not be overstated.***
- → *If your study procedures involve obtaining information that may be clinically relevant (e.g., information obtained from blood draws, validated health screening, DXA scans, etc.), include information about whether individual results will be disclosed to the participant and if so, under what conditions. For example:*

We may learn information about your health as part of the research. We [will/will not] share this information with you [describe how, or why not].

Costs and Compensation **Omit if there are no costs and no compensation.**

You [will/will not] have any costs from participating in this study. [If there will be costs, state specifically what they will be.]

You [will/will not] be compensated for participating in this study. ***If participants will be compensated in any amount, add:*** You 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 you receive.

If the payment is $100 or greater, also include the following language: You will need to provide your social security number (SSN) and address on the form in order for us to pay you.

Optional—can be used to explain why the information is needed*:* This information allows the University to fulfill government reporting requirements. Confidentiality measures are in place to keep this information secure. You may forego receipt of payment(s) and continue in the research study 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 Controller's Department: (515) 294-0457 or http://www.controller.iastate.edu.

- → *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 you decide to not continue your participation in the study, you will be compensated $5 for each visit.).*
- → *Completion of all study procedures cannot be required to receive compensation—it is considered coercive to make completion of the entire study the basis for compensation.*
- → ***If course credit or extra credit will be given to students for participating, please specify the amount of credit and 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 course credit is offered, 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.*

→ *When applicable, list the alternatives to participation that may be desirable to participants (e.g., any other similar programs in which they can participate and receive similar services, alternative treatments/therapies available, etc.).*

Your Rights as a Research Participant

Participating in this study is completely voluntary. You may choose not to take part in the study 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.*

- *ISU 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 effect on you as a student or employee in any way.").*

If applicable to your study, add the following:

- If you withdraw from the study early [Describe procedures for withdrawal, such as return of equipment, any safety concerns related to early withdrawal, or other information participants should know.]
- We may end your participation in the study if [list any foreseeable circumstances and/or reasons that the subject's participation may be terminated.]
- Describe what will happen to data collected up to the point of withdrawal (i.e., will data already collected be retained and used for analysis or destroyed?).

  Note: For **FDA-regulated clinical trials,** *all data collected up to the time of subject withdrawal must be retained in the trial database. Thus, the consent document should inform trial participants that their data will be retained for analysis even if they withdraw.*

If you have any questions *about the rights of research subjects or research-related injury*, please contact the IRB Administrator, (515) 294-4566, IRB@iastate.edu, or Director, (515) 294-3115, Office of Research Ethics, Iowa State University, Ames, Iowa 50011.

Research Injury (This statement MUST be included if there is greater than minimal risk to the subject.) Omit if not applicable.

Please tell the researchers if you believe you have any injuries caused by your participation in the study. The researchers may be able to assist you with locating emergency treatment, if appropriate, but you or your insurance company will be responsible for the cost. [**When applicable, add:** *Eligible Iowa State University students may obtain treatment from the Thielen Student Health Center*.] By agreeing to participate in the study, you do not give up your right to seek payment if you are harmed as a result of being in this study. However, claims for payment sought from the University will only be paid to the extent permitted by Iowa law, including the Iowa Tort Claims Act (Iowa Code Chapter 669).

Confidentiality

Research records identifying participants will be kept confidential to the extent permitted by applicable laws and regulations and will not be made publicly available without your permission. However, it is possible that other people and offices responsible for making sure research is done safely and responsibly will see your information. This includes federal government regulatory agencies, [list all other applicable groups such as the Food and Drug Administration, the funding agency, etc.], auditing departments of Iowa State University, and the Institutional Review Board (a committee that reviews and approves human subject research studies) may inspect and/or copy study records for quality assurance and data analysis. These records may contain private information.

→ ***If the study is regulated by the FDA (it involves research on drugs, medical devices, food additives, etc.), the FDA must be identified above as an entity that may inspect or copy records.***

To protect confidentiality of the study records and data, 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, including video and audio) and any identifiers will be kept confidential (e.g., locked filing cabinet, password protected computer files, how access will be controlled, etc.).]

→ *Be sure to consider any plans to share de-identified data with others in the future (such as may be required as a condition of funding, publication, etc.). Avoid assertions that limit flexibility, like "only the researchers named above will have access to the data".*

→ *Avoid overly specific plans that will quickly become outdated, such as plans to store data in specific locations or limit access to specific people.*

→ *Unless you are absolutely certain that you wish to do so, the IRB recommends that you DO NOT specify any plans to destroy data. Destruction of identifiers is typically sufficient to ensure confidentiality; retaining the de-identified data indefinitely is usually acceptable (and preferable). Destruction of the actual data may be required in highly unusual situations where the data cannot be de-identified and retention presents unreasonable risk to subjects.*

***For NIH-funded research**, add the following text to inform participants about plans to comply with the NIH Inclusion Across the Lifespan Policy reporting requirements:*

Information about your personal characteristics, such as your sex/gender, race, ethnicity, and age, must be reported to the study's funding agency, the National Institutes of Health. The information we report to NIH will not include any information that could identify you.

For research using Amazon Mechanical Turk, add wording such as the following, edited as needed to reflect your plans:

Please be aware that any work performed on Amazon MTurk can potentially be linked to information about you on your Amazon public profile page, depending on the settings you have for your Amazon profile. We will not access any personally identifying information from your Amazon public profile page. We will keep your mTurk worker ID confidential and separate it from the other information you provide to us.

***For all research**, include wording such as the following, edited as needed to reflect your plans:*

To protect your confidentiality when results of the study are reported, the following measures will be taken: [Describe the extent to which participants' identities can or will be kept confidential when results of the study are disseminated. If **confidentiality cannot or will not be maintained, participants should be clearly informed of this**.]

If applicable, include the following information about important limitations to confidentiality:

In cases where you report either abuse/neglect of a minor or dependent adult, or the imminent threat of harm to yourself or others, we may have to break confidentiality by notifying the appropriate authorities to assure the safety of you and others.

If your project has a Certificate of Confidentiality (issued by NIH or CDC), include the following:

Certificate of Confidentiality **Omit if not applicable.**

Identifying information gathered about you during this research project is protected by a Certificate of Confidentiality from the [Agency Issuing CoC]. With this Certificate, researchers cannot be forced to share identifying information about you with anyone not connected to the research, even by a court subpoena. The researchers will use the Certificate to resist any court orders or legal demands.

Additionally, identifying information protected by the Certificate will not be shared outside of the research team, except in the following instances:

- If there is a law that requires disclosure (such as to report child abuse or communicable diseases, *but not for legal or other similar proceedings)*;
- If you have consented to the disclosure or sharing of information, including any disclosure or data sharing plans described elsewhere in this consent document; or
- For use in other scientific research, as allowed by federal regulations protecting research subjects; or

- To personnel of the [Funding Agency], when information is needed for auditing or program evaluation; or
- To meet the reporting requirements of the Food and Drug Administration, such as for studies of investigational medical devices or drugs; or
- To authorized individuals at Iowa State University if they need to verify that the research is being done correctly.

In addition, the researchers may share information if necessary to prevent serious harm to you or someone else; for example, if the researchers learn of ongoing child abuse or neglect, or the imminent threat of harm to you or others, they may share this information with the appropriate authorities.

You should know that a Certificate of Confidentiality does not prevent you from voluntarily sharing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

Future Use of Your Information

Describe any known plans to share data with others, such as in a data repository or with collaborators.

In addition, include <u>one</u> of the statements below, adapted as needed to apply to your study, to describe plans for future use of the data:

Information about you, including your biospecimens, will *only* be used by the research team for the project described in this document.

OR

Information about you, including your biospecimens, collected for this study may be shared with other researchers. It may also be used for other research studies. These studies may be similar to this study or completely different. We will make sure that your identity cannot be linked to the information we share. We will not ask you for additional permission before sharing the information.

→ *If biospecimens are collected during your study and will or may be shared, be sure to specify whether future use plans apply to the actual biospecimens or only to data generated from the biospecimens*

→ *If biospecimens are NOT collected during your study, please remove references to sharing biospecimens from the statement you select.*

If biospecimens (even de-identified) could be used for commercial profit, add a statement that the subject's biospecimens may be used for commercial profit, and describe whether the subject will or will not share in this commercial profit. You may use a statement, adapted to reflect study plans, such as:

Biospecimens collected from you for this research may be used to develop products that could be sold in the future. Researchers, their organizations, and other entities, including companies, may potentially profit from the use of the data, biospecimens or discoveries from this research. You will not have rights to these discoveries or benefit financially from them.

*For Clinical Trials that will be registered at ClinicalTrials.gov, add the following statement, **verbatim**:*

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Questions

You are encouraged to ask questions at any time during this study. For further information ***about the study,*** contact [principal investigator name and contact information; ***for a student project,*** the supervising investigator's name and contact information MUST be included].

Your Consent

If signed consent will be obtained, use verbiage similar to the following:

By signing this document, you are agreeing to participate in this study. Make sure you understand what the study involves before you sign. If you have any questions about the study after you agree to participate, you can contact the research team using the information provided above.

I am 18 years of age or over and agree to take part in this study.

If the study involves obtaining identifiable data about participants from private student records (e.g., grades, coursework, data from the Registrar or other offices, etc.), add:

I also agree that the research team may obtain information from my educational records, as described in this document, for the research.

Participant's Name (printed) _____

_____ _____

Participant's Signature Date

If consent will be obtained online (such as by clicking radio buttons), use verbiage similar to the following:

By clicking below, you are agreeing to participate in this study. Make sure you understand what the study involves before you agree. If you have questions about the study after you agree to participate, you can contact the research team using the information provided above.

You may print a copy of this form for your files.

☐ *I certify that I am 18 years of age or over and agree to participate in this research study.*

If the study involves obtaining identifiable data about participants from private student records (e.g., grades, coursework, data from the Registrar or other offices, etc.), add:

☐ *I also agree that the research team may obtain information from my educational records, as described in this document, for the research.*