**Appalachian State University**

**Human Subjects Research Consent Template**

This template is designed to assist principal investigators of non-exempt human subjects research at Appalachian State University in writing clear, effective consent documents that contain the required language from all applicable federal departments and agencies (including the National Institutes of Health, Department of Health and Human Services, and the Food and Drug Administration), North Carolina state law, and University policy. This template is to be used in conjunction with our [elements of consent checklist](https://researchprotections.appstate.edu/sites/default/files/2ele1.doc). In addition, the [procedure-specific text forms](https://researchprotections.appstate.edu/sites/default/files/3pro1.pdf) provide you with examples of language for specific procedures typically reviewed by the IRB. This template should be used for all non-exempt research, and must be used for all more-than-minimal-risk research.

**How to use this template:**

This template has three different types of text which will guide you in constructing your consent form:

1. Black, non-italicized text: This language is required if there is no additional guidance. If the text is only necessary in specific circumstances, these circumstances are in red.
2. Red text: This language contains instructions about the type of information that is necessary and how it should be written. It also describes specific situations that may require specific language. When completing these sections, please remove any language that does not pertain to participants (such as directions for completing the form) and then change the font color to black.
3. *Black, italicized text: Example language. For sections that will require language specific to your study, italicized text provides examples of acceptable language. You can find more example language in the* [*procedure-specific text forms*](https://researchprotections.appstate.edu/sites/default/files/3pro1.pdf)*. Remove all example language that does not pertain to your study. Un-italicize the language you are keeping.*

Lastly, when you see \*\* it means that the template language or instructions only applies in certain circumstances (described in red text) and that section or sentence can be erased if it doesn’t apply to your study. For example, language about mandatory reporting is marked with \*\* and can be erased if it doesn’t apply; however, language about benefits is not marked because all studies should state the benefits of the study, or state that there is no benefit.

**General instructions and suggestions for writing your consent form:**

1. As you go through the template, read all the instructions and template language. Once you have written a particular section, be sure to remove all the instructions in red and any template language not required for your study. If you used any example text, be sure to un-italicize it. Also, delete these first two instruction pages.
2. All consent forms and parental permission forms should be written at the 6-8th grade reading level (or lower) depending on the population of subjects, as assessed using the reading level function in Word (this function may need to be enabled, as explained [here](https://support.microsoft.com/en-us/office/get-your-document-s-readability-and-level-statistics-85b4969e-e80a-4777-8dd3-f7fc3c8b3fd2)). Additionally, you can consult the following sources for guidance for improving the readability of consent forms: (1) [Guidance for Consent Readability](https://researchprotections.appstate.edu/sites/default/files/consent_writing_guidance.pdf) and [(2) Plain Language Resources](https://researchprotections.appstate.edu/sites/default/files/plain_language_dictionaries.docx). You may also use web tools that review your specific text for readability such as [Readable](https://app.readable.com/text/?demo&_ga=2.36794851.259922343.1715121662-804256271.1715121662).
3. The Key Information section is required for all non-exempt consent forms and includes a brief description of the study, detailing the most important information the participant needs to know about the research. Specifically, it tells the participant why they would or would not want to participate in your study.
4. The majority of the consent form—referred to broadly as the “researcher statement”—is written to the participant and must be written in second person (i.e. “you”). The final short section before the participant signs the form is called the “participant’s statement” and must be written in the first person, i.e., from the subject’s perspective.
5. It is important to be concise throughout the consent form. Although you must explain the study in such a way that subjects can understand what they are being asked to do, how long it will take, the possible risks and so on, you do not have to provide the “granular” detailed instructions for every visit. For example, if the study involves the use of a Fit Bit that must be returned to the research team, it is enough to state “You will return the Fit Bit at the end of the study.” You **do not** need to state “We will send you a box with postage paid that you can put the Fit Bit in to send us after the 5th visit. Be sure to write your return address on the upper left hand corner of the box and keep the tracking number.” If you wish to provide participants with a detailed timeline and/or granular instructions for each visit, please provide this information in a separate document, after consent has been obtained (this will reduce the risk of participants feeling overwhelmed during the consent process). As a reminder, all participant-facing materials must be included in the IRB application for review.

# APPALACHIAN STATE UNIVERSITY

**INFORMED CONSENT TO PARTICIPATE IN RESEARCH**

**LIST TITLE OF STUDY**

Researchers: List names, academic/staff positions, divisions/departments, contact information (preferably both telephone numbers and App State email addresses) of lead researcher (PI) and contact person(s) for subjects.

Sponsored by:You must include the external sponsor’s name, if applicable. If there is no external sponsor, you can delete this line. Including internal funding is optional.

## KEY INFORMATION

We are asking you to be in a research study. The purpose of this form is to help you decide if you want to be in this study. Read this form carefully. Please contact researchers listed above with any questions you have about the research.

This study is about [describe study very briefly]. [Describe the time commitment for the study]. You may want to be in the study because/if [reasons to participate]. You may not want to be in the study because/if [reasons not to participate]. \*\*\*NOTE: The purpose of this paragraph is to provide participants with a concise and focused presentation of key study information. The goal is to assist potential subjects with understanding the reasons why they might or might not want to participate in the research, and provide the information most pertinent to their decision of whether to participate.

Being in this study is voluntary. You do not have to participate. Even if you agree to be in the study, you can decide to leave the study at any time. Your choice will not affect your relationship with any members of the research team, with Appalachian State University, nor with (if applicable) [the research site]. You will **not** lose any benefits to which you are entitled if you choose not to be in the study.

## PURPOSE OF THE STUDY

Provide a **brief** background and describe the purpose of the research in **lay-language** (i.e., language that can be understood by regular individuals who are not educated in your field of study) at the 6th-8th grade reading level, or lower.

State a how many people will be in the study (this can be listed as a range, e.g. *60-80 participants*, or as a maximum number of subjects, e.g. *up to 80 participants*). This number range must be the same as the number that has been approved by the IRB.

## STUDY PROCEDURES

At the beginning of this section, provide a brief 1-2 sentence summary of the study procedures and study duration, such as: *This study involves 4, one-hour lab visits over 2 months*. *We will draw your blood, measure your body composition, and ask you to complete surveys. Between visits, you will be asked to wear a wrist monitor while you sleep.*

Describe study procedures in lay language, where they will take place, how long they will take, and total time commitment for the study. If there are multiple visits, briefly describe what will occur at each and how much time there will be between visits. For multiple visits, it may help to use bullet points. You do not need to provide a detailed agenda for each study visit in this section (as long as this agenda will be provided in an appendix or a separate document prior to those visits), but you must ensure that all procedures are listed and that the expected time commitment of each visit is specified (the length can be a maximum, e.g. *up to 4 hours*; or a range e.g. *2-4 hours*; or a reasonably expected length e.g. *about 3 hours*).

While this section must include all details about the study procedures required for an individual to understand what will be asked of them if they agree to participate in the study, it should not include any unnecessary details. If applicable, please instead prepare a detailed study schedule to provide to participants separately from (and preferably *after*) the consent process.

\*\*As appropriate, specify volume or size of samples (e.g., urine, blood, biopsies) to be taken and the names and doses of substances to be given. When communicating with participants, this should be referred to in common measurements (e.g. teaspoons/tablespoons, etc.). For example: *We will collect your blood [number of blood draws] times during the research. We will draw the blood from [location(s) of blood draw]. Each time we draw blood, we will take [amount of blood in teaspoons or tablespoons]*.

\*\*Describe questionnaires, surveys, and interviews and describe or provide examples of the most personal and sensitive questions you will ask.

\*\*State that subjects may refuse to answer any question or item in any test, inventory, questionnaire, or interview, for any reason. If certain questions must be answered in order for participation to continue, inform participants that refusal to answer these specific questions will result in their removal from the research.

\*\*If a participant may be removed from the study for any reason, this must be disclosed in the consent form.

\*\*Describe the use of any medical, academic, or other records, as well as any use of photographs, audio, or visual recordings. \*\*\*NOTE: If HIPAA or FERPA regulations apply to your research, please contact the IRB Office for guidance, as this consent form does not meet the requirements for a release form for either kind of records.

\*\*Broadly discuss how biospecimens will be analyzed, for example: *We will analyze your blood for stress chemicals.* If you will analyze specimens for sensitive information such as drug use or presence of diseases, or if you will sequence human germline or somatic specimens with the intent to generate the genome or exome sequence of that specimen, this **must** be explicitly disclosed in the consent form and the risks to participants as a result of this analysis must be disclosed in the “Risks, Stress, and Discomforts” section below.

## RISKS, STRESS, AND DISCOMFORTS

This section is only for discussing the risks of specific study procedures. You should discuss the magnitude of harm that could occur from each procedure or mode of data collection, and then subsequently discuss the likelihood of that harm occurring. For easy readability, you should list each procedure as a subheading under this section (e.g. “Blood Draws”, “Questionnaires”, etc.) and list the risks of that specific procedure under the subheading.

Include information about the physical, psychological, emotional, legal, financial or economic, academic, or other risks, including side effects, stress, discomforts, breach of confidentiality, or the invasion of privacy that might result from each procedure. Please remember, when talking about privacy - you are talking about the person and their body and when talking about confidentiality you are talking about their data.

**Do not** state that there are no risks. **Do not** use this section to discuss the lack of risks of a specific procedure.

For studies involving blood draws, you must include the following language: Risks of taking blood include some discomfort, bruising, and minor bleeding. Infection, excess bleeding, blood clots, and fainting are also possible, though unlikely. In the rare case of exposure of an experimenter to blood or tissue, we will analyze that blood for HIV and hepatitis. This information will not be shared with you because North Carolina state law restricts the return of clinical results from non-medical providers. This risk will be minimized by having certified phlebotomists draw blood using correct procedures.

\*\*If appropriate, state how side effects of drugs, supplements, devices, or other interventions will be handled.

\*\*If drugs are used, state that there may be unanticipated and unknown side effects.

\*\*If investigational drugs are used, state that you will provide subjects with any information developed during the study that might affect their willingness to participate.

\*\*If radiation exposure is involved, describe the risk using language recommended by the Appalachian State University Environmental Health, Safety, and Emergency Management (EHS&EM).

**\*\*ALTERNATIVES TO TAKING PART IN THIS STUDY**

\*\*For studies involving interventions (educational, social, medical, or other) within activities in which subjects are already participating (clinical care, education, athletics programs), include descriptions of alternative procedures or standard care that are available if a subject chooses not to be in the study. Example: *If you do not participate in this research, you can still attend class as you normally would, but you will not receive text-messaged quizzes on course content each morning.*

**BENEFITS OF THE STUDY**

Describe the expected benefits to individual subjects and/or society. Explicitly state if subjects will not benefit from being in this study: You will not receive individual benefit from participating in this study. Note that compensation is never considered a benefit of the research; never discuss compensation in this section.

**\*\*RETURNING RESULTS TO YOU**

If the study will produce any clinically relevant research results, describe whether these results will be given to the subjects, and if so, under what conditions. Describe whether and how subjects can opt out of receiving results.

Make sure to note that the results are **not** intended for diagnosis, **will not** be interpreted by the study staff, and that they should be discussed with medical providers if the participant has any questions about their results.

**\*\*SOURCE OF FUNDING**

\*\*For research receiving external funding or other type of external support, state: The study team and/or Appalachian State University is receiving [financial support, OR describe other type of support such as “the study drug”] from [insert sponsor’s name].

**\*\*FINANCIAL CONFLICT OF INTEREST**

\*\*State if any of the researchers have a financial conflict of interest in the results of the study. This section is required when any investigator has a Financial Conflict of Interest as defined by ASU Policy 604.6. If there is no Financial Conflict of Interest, this section should be erased.

[Investigator name] has a financial or other relationship with [company name]. There is a Conflict Management Plan in place to reduce the possible effects of this relationship on your safety and welfare.

## PROTECTION OF RESEARCH INFORMATION

If you will be collecting any identifiable or easily re-identifiable information, state: The research team will collect identifiable data about you. *Identifiable data* means information about you that is linked with identifiers (such as your name, ID, or a unique story about you). *Identifiers* are pieces of information that can be used to directly or indirectly identify you. This section describes how we will protect this information.

State whether the data that will be collected and stored will be:

* Confidential—researchers store data with identifiers (including direct and indirect identifiers), or separate from identifiers and linked with a code.
* Collected without identifiers—researchers have contact with the subjects, but do not collect identifiers (other than, if applicable, signatures on the consent forms).

Describe how data and specimens will be protected, such as by separating data from identifiers and having them linked by a code, using University-protected storage and computers, locking files or specimens in a safe in a locked office, etc.

\*\*If you will keep any data or biospecimens indefinitely, describe what will be kept and the identifiability of those data or biospecimens.

\*\*If you will eventually destroy identifiers, or the link between identifiers and study data, state when the identifiers will be destroyed in relation to the end of the study producers and all analyses. For example, *We will keep a link between your identity and the data we collect from you. This link will be deleted after this research has been accepted for publication. After we delete this link, we will no longer be able to know which data came from you.*

\*\*State who or what other agencies (sponsors, other researchers, etc.) will have access to identifiable data and why. Do not make statements to the effect that only the research team will have access to the data.

For all studies in which links between subjects’ identities and the data will be retained, for any period of time, add:Research studies, like this one, are sometimes reviewed to make sure they are being done safely and legally. If a review of this study takes place, people who are not on the study team may look at your identifiable data.

\*\*For drug and medical device studies regulated by the U.S. Food and DrugAdministration, add:The U.S. Food and Drug Administration (FDA) reserves the right to review study data that may contain identifying information.

\*\*Describe any limits to confidentiality (for example if study procedures may elicit information about child abuse, elder abuse, or harm to self or others). For example, you might state: *The information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we must report that to the authorities.*

\*\*You must disclose any mandated reporting obligations that may affect confidentiality. For example: *If you tell the researchers of child abuse or neglect, they are required to report this.*

\*\*For studies that are required to be listed in the federal clinical trials registry at [www.clinicaltrials.gov](http://www.clinicaltrials.gov), federal law requires that the following statement be included, without any revision: 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.

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**\*\*USE OF DATA OR BIOSPECIMENS FOR COMMERCIAL PROFIT**

Consider whether biospecimens collected for this study may ever be used for commercial profit. Consider all sources of profit: this study as well as any future potential uses, for example if the specimens will be added to a repository and used by other entities. If biospecimens (whether identifiable or deidentified) may be used for commercial profit, insert the following, or similar, language: The [describe type of biological samples: e.g. urine, blood, sweat, etc] samples we collect as part of this research may be used for commercial profit. Choose as appropriate: There is no plan to share this profit with you. or There is a plan to share this profit with you. [Please describe the plan for sharing profit].

**USING YOUR DATA IN FUTURE RESEARCH**

If you or others will never use information and specimens from this study for future research state: The information collected as part of this research will not be used or distributed for future research. If applicable: The [describe type of biospecimens, e.g. urine, blood, etc.] samples we collect from you will also not be used or distributed for future research.

If there is **any possibility whatsoever** that information and/or specimens from this study will be used for future research (this applies to most studies) or put in a repository for future research, state: After we remove identifiable information, we may share the information and/or [describe type of biospecimens, e.g. urine, blood, etc.] samples we collect from you. Your de-identified information and (if applicable) biological samples may be used for future studies and/or shared with other investigators without getting additional permission from you. We will remove all identifiers before sharing any information or [describe type of biospecimens, e.g. urine, blood, etc.] samples outside the research team.

**FOR HELP REGARDING RESEARCH-RELATED HARMS**

For all studies, state whom the subject should contact in the event of study-related injury, illness, harm, distress.

\*\*For more than minimal risk studies, the remainder of this section is required; if your study is no more than minimal risk, the remainder of this section may be deleted if not otherwise applicable.

In the event you become hurt or sick as a result of your participation in this study, we will follow standard emergency procedures. If you get hurt or sick when you are not at the research site, please call your doctor or (in an emergency) call 911. If your illness or injury could be related to the research, tell the doctors or emergency room staff about the research study. Provide them with a copy of this consent form if possible. When you are able, please call the Principal Investigator (PI name and phone number) to tell them about your injury or sickness.

\*\*Inform subjects about whether any medical treatment is available if an injury occurs and, if so, what it consists of, or where further information can be obtained.

By signing this document, you are **not** waiving any legal rights that you have to act against Appalachian State University for harm or injury resulting from negligence of the University or its investigators.

## \*\*COMPENSATION

If participants will be compensated, describe the amount of the payment and explain whether the payment will be made in whole (regardless of whether the participant completes the study) or be pro-rated by visit/procedures. If compensation exceeds $99.99 for a single study or $599 for participation in multiple studies in a calendar year include the statement: University policy requires the collection of Social Security numbers (or Appalachian Banner ID numbers) before we can pay you.

## YOUR RIGHTS AS A RESEARCH PARTICIPANT

It is your decision whether or not you will participate in the research. If you do not participate in the research, there will be no penalty. You will not lose any benefits or rights you would normally have. If you choose to be in the research, you can change your mind at any time and withdraw from the research. If you agree to be in the research but change your mind later, please [detail withdrawal procedures, e.g. *let the researcher know, stop completing the survey*, etc.].

If you have questions or concerns about your rights as someone taking part in research, please contact the Appalachian State University IRB Office at **828-262-4060** or [**irb@appstate.edu**](mailto:irb@appstate.edu).

If this study is non-exempt, include the following: This study was approved by the Institutional Review Board (IRB) on [date of approval]. Choose one of the following, as appropriate: This approval does not expire. or This approval will expire on [expiration date of approval] unless the IRB votes to renew approval.

If you are requesting an exemption determination, please state: This study is exempt from the federal regulations governing research with human subjects but it was reviewed by the Appalachian State Research Protections Staff in accordance with ASU Policy 209.

Participant’s statement

By signing below, I agree to participate in this study and agree that:

* The purpose and procedures of the study have been explained to me.
* I have been informed of the risks of participation.
* Participation is voluntary.
* I do not have to participate and can leave the research at any time.
* I have had the opportunity to ask questions.
* Any questions I have about the research were answered to my satisfaction.
* If I have any questions later, I can contact the researchers listed on the first page of this form.
* If I feel that I have been harmed by participating in this study, I will contact one of the researchers listed on this form.
* I have been given (or have been told that I will be given) a copy of this consent form to keep.

Signatures are required for non-exempt research unless the IRB approves a waiver of written documentation of consent. Signatures are not required for exempt research unless that research is seeking access to FERPA data (if this is the case, please contact the IRB office at [irb@appstate.edu](mailto:irb@appstate.edu) for guidance). If you are requesting a waiver of written documentation of consent or if you are requesting an exemption determination, you may remove the signature lines below and change the above language that references signatures.

Printed name of Participant Signature of Participant

Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_