**Appalachian State University**

**Office of Research Protection**

**Human Subjects Consent and Parental Permission Template**

(version 2.0: 12/21/2020)

This template is designed to assist principal investigators of non-exempt human subjects research at Appalachian State University in writing clear, effective consent documents and parental permission forms that contain the required language from all applicable federal regulations (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. The form is meant 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 form:**

In the following form, you will find 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 circumstance 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.
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)*.*

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 on 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, erase these first two instruction pages.
2. Be sure to complete the researcher footer on the bottom right hand corner of the page.
3. All consent forms should be written at an 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)
4. The majority of the consent form—referred to broadly and in the template as the “researcher statement”—is written to the subject and should be written in the 1st person or 3rd person from the researcher’s perspective. The final short section before a subject signs the form is called the “subject’s statement” and should be written in the 1st person from the subject’s perspective.
5. **If you are using this as a parental permission form:** You will need to change many of the references in the “researcher statement” to say “your child” instead of “you,” e.g. “We will draw 15 ml of blood from your child’s arm.” In addition, there is some specific language noted in the template instructions (in red) that should only be included if the form is used as a parental permission form.
6. It is important to be concise throughout the consent form. Although you should 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 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.”

# APPALACHIAN STATE UNIVERSITY

**CONSENT FORM OR PARENTAL PERMISSION FORM**

**LIST TITLE OF ACTIVITY**

Researchers: List names, academic/staff positions, divisions/departments, contact information (preferably telephone numbers) of lead researcher (PI), contact person for subjects, and faculty advisors (students only).

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

Researchers Statement:

We are asking you to be in a research study. This form gives you information to help you decide whether or not to be in the study, such as the purpose of study; the procedures, risks, and benefits of the study; how we will protect the information we will collect from you; and how you can contact us with questions about the study or if you feel like you have been harmed by this research. Please read it carefully. You should ask any questions you have about the research and, once they are answered to your satisfaction, you can decide whether or not you want to be in the study. Being in the study is voluntary, and even after you agree to participate, you can change your mind and stop participating at any time without losing any benefits from the University [Include and other entities engaged in the research] to which you may be entitled.

\*\*If this form is being used as a parental permission form, state We will also ask your child if they would like to participate in the study. Even if you give permission for your child to take part in the research, we will only include your child in the study if they agree to participate. Your child may change their mind at any time and withdraw from the study by [describe procedures, e.g. telling their teacher, telling the researcher.].

**\*\*KEY INFORMATION ABOUT THIS STUDY**

This section is required when the consent document—without this section and without the signature lines—is greater than 2,000 words (approximately 5 pages, single-spaced, 1-inch margins), or specifically requested by the IRB.

This section is optional for all other studies and consent materials.

Section of 45 CFR 46.116(a)(5)(i) of the Health and Human Services regulations for research human subjects requires that subjects be given a concise and focused presentation of key study information before being given other information. The goal of this section is not simply to provide an abstract or executive summary of the rest of the consent form but to assist potential subjects with understanding the reasons why one might **or might not** want to participate in the research. A comprehensive description of key information would likely include:

* That consent is being sought for research and that participation is voluntary
* A brief summary of the purpose of the study
* Duration of participation
* The main things the study will require of the subject (for example, study procedures, tasks the subject will have to complete, activities the subject will have to avoid)
* The most likely potential benefits
* The risks of participating in the study that would be of most significance to the subject population.

When writing this section, think about what a reasonable person from the study population would want to know and consider the following questions:

* What are the main reasons a subject will want to join this study?
* What are the main reasons a subject will not want to join this study?
* What is the research question the study is trying to answer? Why is it relevant to the prospective subject?
* What aspects of research participation in this particular study are likely to be unfamiliar to a prospective subject, diverge from a subject’s expectations, or require special attention?
* What information about the subject is being collected as part of this research?
* What are the types of activities that subjects will do in the research?
* If applicable, how will the subject’s experience in this study differ from treatment outside of the study?

## PURPOSE OF THE STUDY

Provide a brief background and describe the purpose of the activity in lay-language.

\*\*For more than minimal risk studies, state how many people will be in the study. This number must be the same as the number that has been approved by the IRB.

## STUDY PROCEDURES

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 where we will draw your blood, measure your body composition, and have you complete surveys. Between visits, you will be asked to wear a wrist monitor when 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, 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.

\*\*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.

\*\*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.

\*\*Describe the use of use any medical, academic, or other records, photographs, audio, or visual recordings.

\*\*Broadly discuss how biospecimens will be analyzed, for example: *We will analyze your blood for chemicals produced by your body related to stress.* Specifically state if you will analyze biospecimens for sensitive information such as drug use or sequence human germline or somatic specimens with the intent to generate the genome or exome sequence of that specimen.

## RISKS, STRESS, AND DISCOMFORTS

This section is only for discussing the risks of specific study procedures. Include information on the psycho-social and physical risks, including side effects, stress, discomforts, breach of confidentiality, or the invasion of privacy that might result from each procedure. **Do not** state that there are no risks, that risks are minimal, or that risks are the same as every day life. **Do not** use this section to discuss the lack of risks of a specific procedure.

\*\*If appropriate, state how side effects will be handled.

\*\*If drugs are used, state that there may be unanticipated 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 the 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 not considered a benefit and should not be discussed in this section.

**\*\*SOURCE OF FUNDING**

\*\*For research receiving external funding or other type of external support, state: The study team and/or the 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]. Appalachian State University developed a Conflict Management Plan to reduce the possible effects of this relationship on your safety or welfare.

## PROTECTION OF RESEARCH INFORMATION

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

* Confidential—researchers store data with identifiers, or separate from identifiers and linked with a code.
* Anonymous—researchers have no contact with subjects and do not collect identifiers.
* Collected without identifiers—researchers have contact with the subjects, but do not collect identifiers, including signatures on consent forms.
* Note that data cannot be both anonymous and confidential.
* If you are using a subject pool such as mTurk and Sona, you are encouraged not to state that data are anonymous, as there are often indirect identifiers associated with these data sets, such as mTurk IDs or embedded IDs.

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, encryption, and locking files or specimens in a safe in a locked office.

\*\*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, *The link between your identifiers and the research data will be retained for the time period required by University policy, and will be destroyed no later than five years after the end of all study procedures and analyses are completed.*

\*\*State who or what other agencies (sponsors, other researchers, etc.) will have access to identifiable data. 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:Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your identifiable data may be examined.

\*\*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). You might state:

*All of 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.*

\*\*If you are a mandatory reporter of juvenile abuse, neglect, or dependency and it is possible that the research could elicit responses that would require mandatory reporting, state: If you tell the researchers of juvenile abuse, neglect, or dependency, they will need to report this to the appropriate authorities.

\*\*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 site 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 specimens we collect as part of this research may be used for commercial profit. Choose one as appropriate: There is no plan to share this profit with you or There is a plan to share this profit with you.

**\*\*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.

**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 and/or [if applicable] biospecimens collected as part of this research will not be used or distributed for future research studies.

If it is possible 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: The information and/or specimens that we obtain from you for this study might be used for future studies. We [will/will not] remove anything that might identify you from the information and specimens. If we do so, that information and specimens may then be used for future research studies or given to another investigator without getting additional permission from you.

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

\*\*In the event you become injured 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, you should call your doctor or call 911 in an emergency. If your illness or injury could be related to the research, tell the doctors or emergency room staff about the research study, the name of the Principal Investigator (PI name), and provide a copy of this consent form if possible. Please call the PI (PI name and phone number) and inform them about the injury.

\*\*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.

\*\*You or your insurance company will be responsible for any costs for medical care. No other compensation is offered by Appalachian State University for injuries gained due to this study.

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: Current University policy requires the study to collect Social Security numbers (or Appalachian Banner ID numbers) for compensation purposes.

## YOUR RIGHTS AS A RESEARCH PARTICIPANT

Your participation in this research is completely voluntary. If you choose not to participate, there will be no penalty and you will not lose any benefits or rights you would normally have.

If you choose to take part in the research, you can change your mind at any time and stop participating. If you agree to participate but decide later that you don’t want to be in this study, please [detail procedures with of withdrawal, e.g. *let the researcher know, tell your teacher, 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 Office of Research Protections at **828-262-4060** or [**irb@appstate.edu**](mailto:irb@appstate.edu).

The IRB will insert the approval date (and expiration date, if applicable) here.

Subject’s statement

By signing below, I volunteer for 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;
* The study is voluntary, I do not have to participate, and I can withdraw at any time;
* I have been given (or have been told that I will be given) a copy of this consent form to keep.
* I have had the opportunity to ask questions, and was able to get all of my questions satisfactorily answered;
* If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form.

Some or all of the signature lines can be removed depending on if you will be seeking written documentation of consent. Consent forms for studies only involving online surveys should remove all signatures.

\*\*Printed name of subject Signature of subject Date\_\_\_\_\_\_\_\_\_\_\_\_\_

\*\*When subject is a minor:

\*\*Printed name of parent Signature of parent Date\_\_\_\_\_\_\_\_\_\_\_\_\_

\*\*When subject is not able to provide informed consent:

\*\*Printed name of representative Signature of representative Date\_\_\_\_\_\_\_\_\_\_\_\_

\*\*Relationship of representative to subject

Copies to: Researcher

Subject