PEPPERDINE
UNIVERSITY

IRB TEMPLATE
BIOMEDICAL ADULT PARTICIPANT CONSENT FORM

The following instructions and examples are provided to assist in development of the Adult Participant Biomedical Consent Form. Additional templates and information are available from the IRB and website.

The following should be considered when developing the consent form:

- Consent forms must include clear identification of the responsible institution (Pepperdine University letterhead as shown above can be utilized or Departmental specific letterhead). **Consent forms submitted without identification of the responsible institution will result in delay of approval of the project.**

- All forms should be submitted suitable for reproduction (printed single sided or available electronically) using at minimum reasonable 12-point font and 1 inch margins.

- Each page of the consent form should be full without inappropriate divisions: sections can be split (some on one page, some on another page) so that large blank areas do not exist.

- All pages must include page numbers at the bottom and (if applicable), a participant's initial blank.

- The informed consent form must be written in the second person. When combined with conditional language, utilization of the second person personalizes the consent form and reflects the existence of voluntary decision making on the part of the prospective subject.

- The informational content of the elements of informed consent should not be mixed or repeated unless necessary. Information presented under any given element should be reasonably complete and restricted to content appropriate to that element. This helps the prospective subject focus on each individual element of consent thereby increasing the validity of the consent process.

- The consent form must be written in simple enough language so that it is readily understood by the least educated of the subjects to be utilized. Normally the highest level of language in the consent form should equate to an eighth grade standard. Scientific terms should be avoided when possible. If scientific terms will be included, the lay term or definition should be provided.

- Please remember, age of majority in California is 18 years old. Anyone younger than 18 requires parental consent/assent or a waiver of parental consent must be approved by the IRB.

- ***Before submitting the consent document for IRB approval, delete this page and all comments/instructions/boxes or non-applicable language. Please also make sure that the content on the consent document is coherent with the information provided on your IRB application.***

IRB #:

Participant Study Title:

Optional: If the formal study title is too long or includes technical terminology, you may consider creating a brief title that participants will better understand.

Formal Study Title:

List the title in this section exactly as it appears on the IRB Application.

Authorized Study Personnel

List by name those personnel authorized to document consent as listed in the IRB Application. Use the following personnel labeling: Principal Investigator and Secondary Investigator(s). Include day phone numbers for all listed individuals. For greater than minimal risk studies, consider including night/home phone numbers and/or other direct contact mechanism. List other study personnel and contact information as appropriate.

Principal Investigator: John Smith, MA Office: (402) 472-1000 **Secondary Investigator**: Jane Doe, Ph.D. Office (402) 472-2000

Key Information:

The 2018 changes to the Common Rule (45 CFR 46) require that consent forms "must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research." This key information is only required to be included for non-exempt research (i.e. Expedited or Full Board review).

Note to PI: Please modify the following section accordingly based on your study.

If you agree to participate in this study, the project will involve:

(Males/Females) between the ages of (age range)
Procedures will include (Summary of X procedures)
(X) number of visits are required
These visits will take a (X) amount of hours total
There are minimal/greater than minimal risks associated with this study
You will be paid (X) amount for your participation
You will be provided a copy of this consent form
Your participation is voluntary and you may decide not to participate at any time

Invitation

Invite the prospective subject to participate in the study using the following standard invitation to participate.

You are invited to take part in this research study. The information in this form is meant to help you decide whether or not to participate. If you have any questions, please ask.

If the study involves collection of Private Health Information (PHI), use the following standard clause.

It also explains how health information will be used for this study and for other research in the future, and requests your permission to use your health information.

Why are you being asked to be in this research study?

Explain succinctly and simplistically why the prospective subject is eligible to participate. As appropriate, major eligibility criteria may be included in this section.

Example: You are being asked to be in this study because you are 19 years or older and you exercise more than twice per week.

If pregnant or breast feeding women are excluded from this study, include the following standard statement.

If you are pregnant, nursing an infant, or plan to become pregnant during this study, you may not be in this study.

What is the reason for doing this research study?

This section should state the scientific purpose of the study. If appropriate, brief background material may be provided to help the potential subject understand why the research is being done. The information should be provided in simplistic language without reference to the subject.
****If your planned project falls under FDA requirements and will be reviewed/approved by the UNMC IRB, please also describe in the section, the FDA approval status of all test articles (drugs, devices or biologics which are being evaluated in this research).***

Example: Adults who exercise more than twice per week generally have a lower body mass index and stronger bone structure. This research is designed to (1) better understand the effects of exercise on your body and bone structure (2) determine whether eating a supplement increases the effectiveness of exercise.

This study is being done at the Pepperdine University [if multi-institutional, add additional site names]. A total of about [total number of participants at all sites] people will participate in this study. About [total number of participants to be enrolled locally] will take part in the study here at Pepperdine University.

What will be done during this research study?

Describe the procedures and their duration chronologically using simplistic language, short sentences or short paragraphs. The use of subheadings may help organize this section and increase readability for studies with a large number of procedures. *The below language is provided for common procedures some times utilized on the Pepperdine University campus, please use as appropriate or add information as necessary.

Example: You will be asked to complete 4 study visits, 1 each week for a total of 4 weeks. During each of these visits, the following will be completed:

Height and Weight: We will ask you to step on a scale to obtain your body weight and height. This procedure will take approximately 5 minutes.

Questionnaires: We will ask you to complete 4 questionnaires, one at each visit. These questionnaires will ask you about your exercise and you how feel during the study. Each questionnaire will take you approximately 10 minutes to complete.

Blood Draw: We will collect a 20 milliliter blood sample (approximately 3 Tablespoons) from a vein in your forearm at each visit. The blood draw will be done by trained personnel. The blood sample will be collected the morning following an overnight fast, which means no food or drink, except water, after 10 pm the night before the scheduled test, and before you exercise. We will analyze your blood to check how the supplement is working in your body. This procedure will take approximately 20 minutes.

Please remember, you must have Institutional Biosafety Committee (IBC) approval prior to completing the procedures with bodily fluids in a human subject research project at Pepperdine University. This may be different if you are completing the collection at a site off campus.

Urine Collection: We will ask you to collect a urine sample during each visit at the lab. We will give you urine collection material (measuring cup and collection tube) and instructions and we will ask you to go to one of the bathrooms in our building to collect the urine. We will record the time and the amount of urine, and we will also analyze your urine to understand how the supplement is working in your body.

Dual X-ray Absorptiometry (DXA): We will measure your body composition (how much fat and muscle your body is made of) with a dual energy x-ray absorptiometry (DXA) scanner at each visit. You will be asked to remove jewelry, body piercings, clothing with zippers or metal buttons, or any clothing containing metal and to put on unrestrictive clothing (provided in the laboratory or brought by you) for the scan. You will lie still on a padded table and breathe normally for the duration of the scan which is approximately 5 minutes for a whole body scan.

Please remember, you must have Radiation Safety approval prior to utilizing ionizing radiation procedures in a human subjects research project at Pepperdine University. However, this may be different if you are completing the procedure at a site off campus.

Pregnancy Testing: If you are female, we will administer a urine pregnancy test prior to this procedure. If the test shows that you might be pregnant, you will not undergo this procedure and may be excluded from the study.

How will my [data/samples/images] be used?

If the research involves collection and/or sharing of data/biospecimens/images to other researchers include the following statements as applicable.

If the research involves collection and/or sharing of de-identified data/biospecimens/images to other researchers include the following statement.

Your [data/samples/images] will be sent to researchers outside of Pepperdine University for [explain why the samples are being sent outside Pepperdine University]. Any personal information that could identify you will be removed before the [data/samples/images] are shared.

If the research involves collection and/or sharing of identifiable data/samples/images to other researchers include the following statement.

Your [data/samples/images] will be sent to researchers outside of the Pepperdine University for [explain why the samples are being sent outside Pepperdine University]. The [data/samples/images] that are sent to these researchers will contain identifiable information including [describe the identifiable information that will be associated with the data/samples/images]. Identifiable information is being sent to these researchers because [explain the purpose of sending identifiable data/samples/images to researchers outside Pepperdine University].

The 2018 changes to the Common Rule (45 CFR 46) require that, for research involving biospecimens, a statement be added regarding (even if identifiers are removed) whether the biospecimens may be used for commercial profit and whether the subject will or will not share in the commercial profit.
****Please note, it is the general policy of Pepperdine University not to allow participants to share in commercial profit. If there are compelling circumstances to allow for sharing of commercial profit with the participant, language will need to be developed dependent on discussion with the IRB and approval from Pepperdine University Ventures.***

Your [specific samples] [may or may not] be used for commercial profit and you will not share in any of the commercial profit from the use of your [specific samples].

The 2018 changes to the Common Rule (45 CFR 46) require that, for research involving biospecimens, a statement be added regarding whether the research will (if known) or might include whole genomic sequencing (i.e. sequencing of human germline or somatic specimens with the intent to generate the genome or exome sequence of that specimen).

Your [specific samples] collected for this research will be analyzed for the study. As part of the analysis, the research [will or might] include [whole genomic/germline/somatic/and/or exome sequencing]. This means that the researchers [will or might] look at your sample to learn about your genes (DNA). There

are different ways to look at your DNA. Researchers often use a technology called sequencing to look at your DNA. Sequencing "reads" each letter of the DNA and finds changes (also called "variations" or "mutations") in your genes that may cause disease or affect how your body reacts to a certain disease.

OR

Your [specific samples] that are collected for this research study will not include [whole genomic/germline/somatic/and/or exome sequencing]. This means that the researchers have no plans to look at or try to "read," the protein information that makes up your genes (DNA) from your sample.

If the research project involves optional sample donation, please note that the below provides initial blanks for the participant to indicate agreement with the optional procedures.

Optional Sample Donation: You will be given the option to donate your [data/biospecimen/images] for future analyses related to this study. Please choose one of the following by placing your initials:

_____I give permission for my [data/biospecimen/images] to be used for this research study, and to be analyzed in the future for additional analysis or for other relevant substances which relate to the study outcomes. Furthermore, I understand that under no circumstances will my samples be used for DNA analysis or genetic research purposes without my expressed written consent. I understand that my samples can be stored indefinitely.

_I give permission for my [data/biospecimen/images] to be used for this research study only. I do not give permission for any future use or any use beyond the scope of this research study. I understand my samples will be destroyed within [X year(s)] after completion of this study.

Will I be notified if my [data/samples/images] result(s) in an unexpected finding?

The 2018 changes to the Common Rule (45 CFR 46) require that, if applicable, a statement be added regarding whether or not clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.
****Note, if you are conducting an MRI at the Center for Brain Biology and Behavior (CB3), you must utilize the MRI incidental findings language that is already available from the department.***

If no clinically relevant research results will be shared, include the following statement.

When [data/biospecimens/images] are collected and analyzed, there is the chance of finding something unexpected. There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as feeling worried about a finding for which no treatment is required or appropriate).

The results from the [data/biospecimens/images] we collect in this research study are not the same quality as what you would receive as part of your health care. The

[data/biospecimen/image] results will not be reviewed by a physician who normally reads such results. Due to this, you will not be informed of any unexpected findings. The results of your [data/biospecimens/images] will not be placed in your medical record with your primary care physician or otherwise. If you believe you are having symptoms that may require care, you should contact your primary care physician.

If clinically relevant research results will be shared, include the following statement.

When [data/biospecimens/images] are collected and analyzed, there is the chance of finding something unexpected. There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as feeling worried about a finding for which no treatment is required or appropriate).

In this study, you will be informed of any unexpected findings of possible clinical significance that may be discovered during review of results from your [data/biospecimens/images]. The results of your [data/biospecimens/images] will not be placed in your medical record with your primary care physician or otherwise.

The results from the [data/biospecimens/images] we collect in this research study [are/are not] the same quality as what you would receive as part of your health care. The [data/biospecimens/images] will be reviewed by a physician who normally reads such results and they will inform us if there are any unexpected findings and we will provide you with this information so that you may discuss it with your primary care physician. However, if you believe you are having symptoms that may require care prior to receiving any information from this study, you should contact your primary care physician.

[Also think about adding a check box as an option for participants to select whether or not they want to receive significant findings- depending on the project parameters].

If the research is conducted concurrently with standard of care, include one of the following statements.

If you take part in this study, the main difference between your regular care and the study is [describe].

OR

This study is not part of your health care.

What are the possible risks of being in this research study?

Please state the risks associated with your study here and indicate the level of the risks – No

more than minimal/minimal to moderate/moderate to substantial

> ***Identify each intervention with a subheading and then state the associated risk(s) using simplistic language. The most serious and common risks should be addressed first followed by disclosure of uncommon and less serious risks in a separate paragraph, if warranted.***
> ***If the study involves use of drugs (FDA/UNMC review), consider including language regarding contraception interaction as appropriate.***

Example: This research presents a slight risk of loss of confidentiality since your blood and urine samples will be able to be identified [and/or shared with researchers from outside Pepperdine University].

There is a possibility that you will feel hungry and uncomfortable during the fasting the night before each visit, and it may be inconvenient for you to not eat anything. Although the supplement that will be provided to you is commercially available and is used by many individuals including elderly and hospital patients, it may upset your stomach and make you feel nauseated.

The risks associated with blood draw include discomfort at the site of the blood draw, feeling dizzy and nauseated, and bruises and blot spots under the skin. Clotting of the blood, blocking of arteries, and infections are very rare but are also potential risks. These risks will be reduced or eliminated by having only trained staff (a nurse or trained phlebotomist) draw blood. Additionally, a trained assistant will closely monitor you while you lay down to have your blood collected. Blood will be drawn in the laboratory in a sterile (clean) environment.

The amount of radiation exposure received as a result of a whole-body DXA scan is similar to that received in about [number of hours] of natural background radiation and about [percentage or fraction] of that received during a one-way flight from New York to Los Angeles. This level of radiation dose is well below known minimum amounts that would result in a direct harmful effect (for example, skin redness or rash). One possible indirect effect to radiation exposure is an increased risk of cancer, but the low level of radiation used in this study is very small. Based on the most current scientific understanding, the excess cancer risk from this procedure is on the order of [%], which can be compared to the baseline risk of developing cancer in the general public of [%].

It is possible that other rare side effects could occur which are not described in this consent form. It is also possible that you could have a side effect that has not occurred before.

What are the possible benefits to you?

> ***If direct subject benefits can reasonably be anticipated as a result of participating in the study, then describe these possible benefits. Conclude with the following standard clause.***

[Description of benefits]. However, you may not get any benefit from being in this research study.

If direct subject benefits are NOT anticipated, then use the following standard clause.

You are not expected to get any benefit from being in this study.

What are the possible benefits to other people?

State the possible benefits to society in terms of advancement of knowledge and/or ultimate possible benefits to persons in the prospective subjects' position.

Example: The benefits to science and/or society may include better understanding of how exercise and this supplement can help others achieve a healthier BMI or bone strength.

What are the alternatives to being in this research study?

Describe in reasonable detail, alternatives the prospective subject may have available or, if nothing else to include, use the following standard clause.

[Describe alternatives] OR: Instead of being in this research study you can choose not to participate.

What will being in this research study cost you?

This section should state the financial obligations the subject may incur as a result of participating in the study. If there are no financial obligations to the subject, then use the following standard clause.

There is no cost to you to be in this research study.

Will you be compensated for being in this research study?

If the subject will receive compensation for participating in the research, state the amount of compensation and conditions for payment. A prorated payment system should be used when appropriate and commensurate with the degree of participation required. If no compensation will be provided, state that.

Example: You will receive $50.00 for each study visit completed. If you complete all study visits, you will receive $200.00.

Who is paying for this research?

For commercial studies, use one of the following standard clauses.

The sponsor of the research is [name of sponsor]. Pepperdine University receives money from the sponsor to conduct this study.

OR

The sponsor of the research is [name of sponsor]. Pepperdine University receives money from the sponsor to conduct this study. The investigator receives a small payment from the sponsor which is used for…[for example, education purposes].

For studies supported by extramural or intramural research grants, use one of the following standard clauses.

This research is being paid for by grant funds from [name of granting agency]. Pepperdine University receives money from [name of granting agency] to conduct this study.

OR

This research is being paid for by grant funds from [name of granting agency]. Pepperdine University receives money from [name of granting agency] to conduct this study. The investigator receives a small payment from [the granting agency] which is used for [for example, educational purposes].

For NIH funded cooperative group studies, use the following standard clause.

Pepperdine University receives money to provide administrative support for the [name of cooperative group] studies. No money is provided specifically for the conduct of this study.

For unfunded studies, include the following as applicable.

This research is being paid for by [name of specific Department/Center/College].

What should you do if you have a problem during this research study?

Your estimation of risk determines what additional information you will include in this section. For studies classified as minimal risk, use the following standard clause.

Your welfare is the major concern of every member of the research team. If you have a problem as a direct result of being in this study, you should immediately contact one of the people listed at the beginning of this consent form.

[Think about also providing resources to participants dependent on the project parameters. For example, provide them with student health or wellness contact information].

For studies classified as greater than minimal risk, and are NOT commercially sponsored, use the following standard clause.

If you have a problem or experience harm as a direct result of being in this study, you should immediately contact one of the people listed at the beginning of this consent form. If needed, seek immediate emergency care for this problem. Please note, it is the policy of Pepperdine University not to pay for any required care. Agreeing to this does not mean you have given up any of your legal rights.

You or your insurance company will need to pay for any costs. The costs for any other medical problems unrelated to this research study are also your responsibility. There are no plans to provide payment for things like lost wages, disability or discomfort. Agreeing to this does not mean you have given up any of your legal rights.

[Think about also providing resources to participants dependent on the project parameters. For example, provide them with student health or wellness contact information].

For studies classified as greater than minimal risk, and ARE commercially sponsored, use the following standard clauses.

If you have a problem or experience harm as a direct result of being in this study, you should immediately contact one of the people listed at the beginning of this consent form. If needed, seek immediate emergency care for this problem. Please note, it is the policy of Pepperdine University not to pay for any required care. Agreeing to this does not mean you have given up any of your legal rights.

[Insert commercial sponsor language, clearly stating the extent and limitations of any possible compensation from them].

[Think about also providing resources to participants dependent on the project parameters. For example, provide them with student health or wellness contact information].

How will information about you be protected?

Begin with the following standard clause.

Reasonable steps will be taken to protect your privacy and the confidentiality of your study data.

Next, if the research requires collection of sensitive information (socially, financially, legally or otherwise) from the prospective subject, follow the introductory standard clause above with a brief description of the precautions which will be utilized to protect the data.

For projects that collect paper-records use this standard clause.

The data will be stored in a locked cabinet in the investigator's office and will only be seen by the research team during the study and for XX years after the study is complete.

For projects that collect electronic records use this standard clause. Describe the security in detail so the participant can understand what protections are in place.

The data will be stored electronically through a secure server and will only be seen by the research team during the study and for XX years after the study is complete.

Finally, for all protocols, conclude with the following standard clause.

The only persons who will have access to your research records are the study personnel, the Institutional Review Board (IRB), and any other person, agency, or sponsor as required by law. Information from this study may be published in scientific journals or presented at scientific meetings but the data will be reported as group or summarized data and your identity will be kept strictly confidential.

HIPAA Information (Personal Health Information) Access

If your project involves collection, use, access or creation of PHI/HIPAA information, use the following standard clauses or the PHI Authorization template located on the IRB templates webpage.
****If you are working with a covered entity outside of Pepperdine University, you may want to consider utilizing their PHI authorization template.***

You have rights regarding the privacy of your medical information collected before and during this research. This medical information, called "protected health information" (PHI), typically may include, depending upon the nature of this research, demographic information (like your address and birth date), the results of physical exams, blood tests, x-rays and other diagnostic and medical procedures, as well as your medical history.

By signing this consent form, you are allowing the research team to have access to your PHI. The research team includes the investigators listed on this consent form and other personnel involved in this specific study at [add additional personnel/institutions as applicable].

Your PHI will be used only for the purpose(s) described in the section "What is the reason for doing this research study?"

Your PHI will be shared, as necessary, with the Institutional Review Board (IRB) and with any person or agency required by law. You are also allowing the research team to share your PHI with other people or groups listed below all of these persons or groups listed below are obligated to protect your PHI.

-Researchers at [name of institutions] involved in this study ***[list this for multi-institution study where PHI will be shared with other researchers]***

-Your health insurance company ***[list this if Pepperdine University is expecting third party payers to pay for clinical procedures performed in the course of the research]***

-The Food and Drug Administration (FDA) ***[list this for FDA regulated research]*** The sponsor [name of sponsor] which provides funds to Pepperdine University to conduct this research ***[list this if the research is sponsored]***

-Data Safety and Monitoring Committee/Board (DSMB/DSMC) ***[list this if the research is sponsored and/or requires a DSMB/DSMC]***

You may cancel your authorization for further collection of PHI for use in this research at any time by contacting the principal investigator in writing. If you cancel this authorization, you will no longer be able to participate in this research.

Use one of the following standard clauses depending on planned length of access to PHI. Provide initial blanks for participants to indicate their authorization.

_____ You are authorizing us to use and disclose your PHI for as long as the research study is being conducted.

OR

_____ There is currently no plan to end this study, so your information may be kept and used indefinitely. ***(Generally, this could be used when the research is without a foreseeable end-point (i.e., banking or registry studies).***

What are your rights as a research subject?

Use the following standard clause.

You may ask any questions concerning this research and have those questions answered before agreeing to participate in or during the study.

For study related questions, please contact the investigator(s) listed at the beginning of this form.

For questions concerning your rights or complaints about the research contact the Institutional Review Board (IRB):

- Phone: +1(310)568-2305
- Email: gpsirb@pepperdine.edu

What will happen if you decide not to be in this research study or decide to stop participating once you start?

Use the following standard clause.

You can decide not to be in this research study, or you can stop being in this research study ("withdraw') at any time before, during, or after the research begins for any reason. Deciding not to be in this research study or deciding to withdraw will not affect your relationship with the investigator or with Pepperdine University (list others as applicable).

You will not lose any benefits to which you are entitled.

As applicable, also use the following standard clauses.

If the research team gets any new information during this research study that may affect whether you would want to continue being in the study you will be informed promptly.

The researchers may also make the decision to take you out of the study, even if you want to continue, if:

- Your health changes and the study is no longer in your best interest.
- You do not follow the study rules or no longer meet the requirements to be in the study.
- The study is stopped by the sponsor, IRB, or researchers.

If this project utilizes a specific research treatment, use the following standard clause.

For your safety, please talk to the research team before you stop any research treatments. They will advise you how to stop the treatment most safely. If you withdraw you may be asked to undergo some additional tests. You do NOT have to agree to do these tests.

Documentation of informed consent

Use the following standard clause.

You are voluntarily making a decision whether or not to be in this research study. Signing this form means that (1) you have read and understood this consent form, (2) you have had the consent form explained to you, (3) you have had your questions answered and (4) you have decided to be in the research study. You will be given a copy of this consent form to keep.

Participant Feedback Survey

As part of Pepperdine University's ongoing accreditation efforts, the Association for the Accreditation of Human Research Protection Programs (AAHRPP) standard I-4: The Organization responds to concerns of research participants, encourages the HRPP to conduct evaluation or research participant satisfaction. In order to meet this standard, we have created an online feedback survey. All investigators are now required to include the following statement and survey link in all written informed consent information documents.

Only include the survey if the consent process will be completed via a process not conducted via online procedures. Investigators using online/web-based procedures are NOT required to include this information.

To meet Pepperdine University's ongoing accreditation efforts and to meet the Accreditation of Human Research Protection Programs (AAHRPP) standards, an online feedback survey is included below:

https://forms.gle/nnRgRwLgajYzBq5t7

Participant Name:

_____

(Name of Participant: Please print)

Participant Signature:

_____ _____

Signature of Research Participant Date

Investigator certification:

If applicable, include the following investigator certification clause. (Generally utilized for greater than minimal risk studies).

My signature certifies that all elements of informed consent described on this consent form have been explained fully to the participant. In my judgment, the participant possesses the capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate.

Signature of Person Obtaining Consent	Date