|  |
| --- |
| **INSTRUCTIONS** (delete this text box once editing is complete)   * This template is intended for studies that can be explained to participants with a consent process/form **using 2,000 words or less**. It is UW IRB policy that because they are shorter, these forms don’t need a distinct [Key Information](https://www.washington.edu/research/hsd/guidance/consent/#5) section. For very simple and very low risk studies, it might make more sense to start with the template for [Exempt Research](https://www.washington.edu/research/forms-and-templates/template-exempt/) and add information as needed. * This template includes the basic required consent elements. Additional elements may be required depending on the specifics of the study. [Designing the Consent Process](https://www.washington.edu/research/hsd/guidance/consent/design) provides discussion and context about each element. The worksheet [Consent Requirements and Waivers](https://www.washington.edu/research/forms-and-templates/worksheet-consent/)provides a short checklist of each element. * [Red bracketed text] is instructional. Delete it after editing is complete. * (Text in parenthesis) indicates there is a choice to be made about which language to include. Delete anything that is not relevant and remove parentheses after editing is complete. * The template is highly editable and can be used to create a form to provide to participants (in hard or electronic copy) or adapted for use as an oral consent script or consent talking points. * Using a UW IRB template is **not** required. We encourage researchers to be creative about designing a consent process and form that is focused on the perspective of the participants and what participation would mean for them. We provide [Example Consent Forms](https://www.washington.edu/research/forms-and-templates/example-main/) that demonstrate different approaches to presenting consent information. * Review the [General Requirements for Consent](https://www.washington.edu/research/hsd/guidance/consent/design/#2). * Formatting choices can have an important impact on facilitating consent comprehension: use 11+ point font; avoid using italics; use 1.5 spacing or more; consider using bullets, tables, schematics, side-by-side comparisons, etc. rather than dense blocks of text. * Use active voice and “plain language”. Avoid technical and medical jargon. Kaiser Permanente’s [PRISM Readability Toolkit](https://www.kpwashingtonresearch.org/about-us/capabilities/research-communications/prism) is a good resource as is this [5 minute video](https://www.youtube.com/watch?v=RL6HHWQTsaI&feature=youtu.be) from Washington University in St. Louis. Keep in mind that the average American reads at a 7th to 8th grade reading level according to the Literacy Project. * With a few exceptions, template language may be edited. Template language that cannot be edited is called out in this template and in the guidance on Designing the Consent Process. * The IRB may consider waiving elements if they meet the criteria described in the guidance on [Waivers or Alterations of Consent](https://www.washington.edu/research/hsd/guidance/consent/design/#4). * For most minimal risk studies, the IRB can approve a waiver of documentation of consent. This means it is not necessary to obtain the participant’s signature. Review the guidance on [Waivers or Alterations of Consent](https://www.washington.edu/research/hsd/guidance/consent/design/#waivedoc) for more information. |

****INFORMATION ABOUT A UNIVERSITY OF WASHINGTON RESEARCH STUDY

[Insert study title]

## What is this study about?

[Review the guidance,[Designing the Consent Process](https://www.washington.edu/research/hsd/guidance/consent/design/#about) for more information.]

We are conducting this study because [Insert a brief description of the purpose of the research. Depending on the study design, you may want to include information about eligibility criteria so the participants understand why they have been approached.].

## What will you be asked to do?

[Review the guidance, [Designing the Consent Process](https://www.washington.edu/research/hsd/guidance/consent/design/#todo) for more information.]

If you decide to be in this study, we will ask you to [Insert a description of the study procedures which may include screening procedures and/or follow-up procedures. It may not be necessary to describe every procedure in detail. For example, rather than listing every data collection instrument that participants will complete, it is sufficient to note that participants will complete several surveys/questionnaires and then provide a brief summary of the general content. All experimental procedures must be described. The description should include an estimate of the time commitment for participants. The UW IRB has provided some [Example Consent Forms](https://www.washington.edu/research/forms-and-templates/example-main/)that may help you visualize how to organize this information.].

| **PROCEDURES** [Describing procedures in a table, diagram or some other visual presentation can be more effective than providing dense blocks of text. This table is meant as a demonstration. Researchers should design a table that works for their study specifics.] | **Group A** | **Group B** |
| --- | --- | --- |
| **Baseline procedure** – Details about the procedure. | X | X |
| **Week 1 procedure** – Details about the procedure. | X |  |
| **Week 2 procedure** – Details about the procedure. | X |  |
| **Week 3 procedure** – Details about the procedure. | X | X |
| **Week 4 procedure** – Details about the procedure. |  | X |
| **Week 5 procedure** – Details about the procedure. |  | X |
| **Week 6 procedure** – Details about the procedure. | X | X |

## Why might you want, or not want, to participate?

[Review the guidance,[Designing the Consent Process](https://www.washington.edu/research/hsd/guidance/consent/design/#why) for more information.]

[Rather than a dense block of text, consider whether using tables or a bulleted list is a more clear way to present the pros and cons of participation. List the risks and benefits in order from most common/likley to occur to least common/likely to occur. The UW IRB has provided some [Example Consent Forms](https://www.washington.edu/research/forms-and-templates/example-main/)that may help you visualize how to organize this information.]

[In this section, desribe the reasonably foreseeable psychocological, social, economic, legal, physical, and/or privacy risks. These may include medical side-effects, stress, discomforts, embarrassment, privacy breach or invasion of privacy, discrimination. If applicable, note that the research may involve currently unforeseeable risks. This [guidance](https://www.washington.edu/research/hsd/guidance/consent/#r) provides information about how to assess which risks are reasonably foreseeable. In higher risk studies, including all possible risks may detract from the prospective participant’s ability to focus on the risks most relevant to their decision about whether to enroll (e.g., if the study is investigating an experimental drug, the risks of a blood draw are not likely to be relevant to the enrollment decision). For minimal risk research, risks or burdens that are immaterial or obvious can be omitted (e.g., participants don’t need to be told that they might get bored completing a survey). It is not necessary to state the absence of risk where none exists.]

[If applicable, this may also be a place to describe reasons other than the study risks that may affect a prospective participant’s decisison about whether to enroll. This could include barriers to participation such as having to take time off of work or securing transporation and/or childcare or eldercare in order to attend an in-person study visit. For studies with randomization, some participants may not want to participate if they know they might be assigned to a placebo group. If there are costs to the participant for participating or if the participant will be paid for participating might also be listed in this section. The information provided in this section should be specific to the individuals being recruited for the study.]

[If applicable, describe alternatives to research participation that participants may wish to consider. Review the guidance on [Designing the Consent Process](https://www.washington.edu/research/hsd/guidance/consent/design/#alternatives) for discussion and sample language.] There are other ways to treat[describe patient’s condition and any alternatives to participation].

[For research that includes medical treatment, the alternatives to research participation must include a description of the current standard of care they would be likely to receive if they choose not to particpate in the research. Standard of care may vary depending on the research location and context. Review the [Designing Consent guidance](https://www.washington.edu/research/hsd/guidance/consent/design/#alternatives) for additional discussion and requirements for studies with medical treatment alternatives. Use the following language:] If you choose not to participate in the research, the treatment/care available to you may include [insert possible alternative treatment/care options here]. The research team will discuss these options with you and provide information about the risks and benefits. You may also wish to discuss these options with your doctor.

[If applicable, list the expected benefits to individual participants or society of participating in the research. Review the guidance on [Designing the Consent Process](https://www.washington.edu/research/hsd/guidance/consent/design/#benefits) for discussion and sample language.]

[If participants will receive payment (i.e., reimbursement, compensation, incentives) for participating in the research, consent must include the following information: **(1)** total payment amount/value; **(2)** schedule/timing; **(3)** type (reimbursement, compensation, incentive); **and (4)** whether it will be pro-rated. Review general guidance on [Subject Payment](https://www.washington.edu/research/hsd/guidance/subject-payment/#5d)for discussion and the guidance on [Designing the Consent Process](https://www.washington.edu/research/hsd/guidance/consent/design/#payment) for example language.]

[If participants may incur costs as a result of research participation, review the guidance on [Designing the Consent Process](https://www.washington.edu/research/hsd/guidance/consent/design/#costs)for information about what must be included in the consent form.]

## How will we protect the information you provide?

[Review the guidance, [Designing the Consent Process](https://www.washington.edu/research/hsd/guidance/consent/design/#confidentiality) for more information.]

[Insert, and modify for accuracy, the appropriate statement regarding the confidentiality and identifiability of the study data. Be sure you understand the meaning of anonymous data, [coded data](https://www.washington.edu/research/glossary/coded/), and [identifiable data](https://www.washington.edu/research/glossary/identifiable-data/) and can clearly describe it to participants. Do not include statements to the effect that only the research team will have access to the data as this is rarely true.]

[Bolding the first sentence or first few words of a paragraph can help the reader quickly identify the information that will follow.]

(**The information you provide will be anonymous.** This means that your name will not ever be connected to the data.) **[OR]**

(**We will protect your confidentiality.** We will store your name and other identifiable information separate from the study data. Access to your identifying information will be limited to certain members of the study team and any individuals from the UW [If this is an FDA-regulated drug or device study, the Food and Drug Administration (FDA),] [If applicable list the Sponsor; e.g., National Institutions of Health (NIH),] or other agencies that may need to audit study records. When we publish the results of this study, we will not use your name. [If applicable] If we learn you intend to harm yourself or others, we must report that to the appropriate authorities. [If applicable] Information about the study and your study results may be placed in your [insert as appropriate; e.g., UW medical record]. This means people outside the research such as health insurers, health care providers, and anyone you have authorized to access your records may be able to find out you participated in this study.)

[If you think it is important for your particular study to eventually anonymize the data, you can include the statement below. Be aware of records retention requirements from sponsors or federal agencies that might apply to study identifiers.] The link between your identifiers and the research data will be destroyed (at the end of the study) **[OR]** (after the records retention period required by state and/or federal law).

[If the research involves collection of private, identifiable information or specimens, include one of two required statements about the possibility of secondary research. Modify the statement so that it applies to this specific study, being sure to describe any definite plans for sharing data. For example, if the data will be submitted to a repository, describe those plans including whether the data will be shared with identifying information and the purposes for which the data will be used. The UW IRB recommends allowing for future use of the research data for most studies. If participants will be given the option about whether to consent to future use of information/specimens, the research team will need to come up with a way to document the participant’s decision when no signatures are being obtained on the consent form.]

(**The information and/or samples collected as part of this research will not be used or distributed for future studies.**) **[OR]**

(**The information and/or samples that we obtain from you for this study might be used for future studies.** We may remove anything that might identify you from the information/samples. If we do so, the information/samples may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information/samples that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.)

[If the study has a federal Certificate of Confidentiality, include the following information.]

**We have a Certificate of Confidentiality** from the U.S. federal [insert institution, e.g., National Institutes of Health] which allows us to protect identifiable research information that is stored in the U.S. from legal proceedings or in response to a legal request unless you give us permission to release it. You or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection, including reporting things like child or elder abuse, monitoring by the agencies conducting the research, and others as listed elsewhere in this consent form.

 [If research information will be added to the participant’s medical record, include these two sentences.] Research information that is placed in your medical record may not be protected by this Certificate. Ask a member of the study team for information about what research information will be placed in your medical record.

[For studies that are granted an automatic CoC as a condition of the award, include this statement.] The Certificate expires when the [insert agency] funding for this study ends. Currently this is [date of funding expiration; if there are multiple grants, pick the expiration date furthest out]. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

[For studies that obtain a CoC from applying to the federal agency, include this statement.] The Certificate expires when the study ends. Data collected prior to expiration will continue to be protected.

## What if you want to stop being in this study, or if the researcher decides you should no longer participate?

[This section, and the information included in it, may or may not apply depending on the study design. Review the guidance on [Designing the Consent Process](https://www.washington.edu/research/hsd/guidance/consent/design/#stop)for more information.]

## How will we test, store, and share your information and samples?

[Review the guidance on [Designing the Consent Process](https://www.washington.edu/research/hsd/guidance/consent/design/#specs) for more information.]

[The specific study design will determine which information to include in the consent process/form. For example, some of this information in this section applies only to biological samples. If there is no biological sample collection, delete those sections and edit the section title.]

**The samples we collect as part of this research may be used for commercial profit**, such as developing new tests or products [insert other details as appropriate]. (There is no plan to share this profit with you.) **[OR]** (There is a plan to share this profit with you [insert details].)

[State whether the research will or might include whole genome sequencing.] **We will study your DNA as part of this study.** DNA is in nearly every cell of the body, and it tells your body how to grow, develop, and function using structures called genes. Genes are inherited from your parents. The genes you inherit may explain some of the differences in the way people respond to different diseases. For this study, we may look at your entire DNA code. This is called “whole genome sequencing”. This will help us understand whether certain genes explain [insert information about what you hope to discover].

[If data, such as genomic data, information about a medical condition, or other study data will be submitted to NIH or other repositories, review the guidance on [Designing the Consent Process](https://www.washington.edu/research/hsd/guidance/consent/design/#sharing)to identify information that must be included in the consent form.]

## Will you get to know your research results?

[Review the guidance[Designing the Consent Process](https://www.washington.edu/research/hsd/guidance/consent/design/#results) for more information.]

[If clinically relevant research results will be returned to participants, they must be told: **(1)** whether results will be provided; **(2)** if so, under what conditions; **and (3)** whether/how participants can opt out of receiving results. Review the guidance on [Return of Individual Results](https://www.washington.edu/research/hsd/guidance/results/)for additional details.]

## Other information about this study.

[Review the guidance on [Designing the Consent Process](https://www.washington.edu/research/hsd/guidance/consent/design/#other) for more information.]

**Being in this study is voluntary.** This means that you can refuse to sign up. It also means that if you do sign up, you can decide to stop being in the study at any time without penalty.

[If there is any external funding or other type of external funding support for the research, include this statement.] We are receiving [financial support or describe other type of support such as “the study drug”] from [insert sponsor name].

[For all studies] **If you have been injured or otherwise harmed by participating in this study**, contact a member of the research team at [insert phone and email; for high risk studies, provide a phone number that will be monitored 24 hours a day and inform participants that they can reach a member of the research team 24 hours a day].

[If the research involves *greater than minimal risk to participants*, explain whether compensation or medical treatments are available if a research injury occurs. Industry sponsored studies should use the language provided by the sponsor. For studies involving non-UW institutions, insert compensation language required or recommended by the institution. For UW studies with medical risks, include the [Human Subjects Assistance Program (HSAP) example language](https://www.washington.edu/research/hsd/guidance/consent/design/#compensation).] If you are injured as a result of being in this study, necessary medical treatment will be available to you at [insert name and location of medical facility].

[If this study is considered a clinical trial by FDA or NIH, include this ct.gov statement. This language cannot be altered.] A description of this clinical trial will be available on <https://clinicaltrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

[If applicable, list the number of participants in the study. Review the guidance on [Designing the Consent Process](https://www.washington.edu/research/hsd/guidance/consent/design/#number)for more information.]

[If the UW has issued a Financial Conflict Management Plan and/or if a non-UW investigator has a conflict of interest, review the guidance on [Designing the Consent Process](https://www.washington.edu/research/hsd/guidance/consent/design/#fcoi) for example language to describe the conflict.]

[If electronic documentation of consent will be obtained, include this statement. This language is applicable when using UW ITHS REDCap and UW Docusign and may apply to other situations as well. The language can be modified, as needed.] **A copy of the consent form will be emailed to you at an email address that you provide.** It will be a “PDF” document. Most computers already have PDF viewer software installed, which will allow you to open, read, or print the consent form. The email we send you will include a link to PDF viewer software (such as Adobe Acrobat Reader) in case your computer doesn’t already have it. If you would prefer to receive a paper copy of the consent form at no cost to you, please contact the researcher(s) listed in this consent form.

## What can you do if you want more information?

[Review the guidance on [Designing the Consent Process](https://www.washington.edu/research/hsd/guidance/consent/design/#info) for more information.]

**Talk to the study team**.We are here to help you understand the study. Please ask us any questions you may have, even about things that are not in this document. It is our responsibility to give you the information you need to make a decision and to give you time to think about whether or not you want to sign up.

**Talk to someone else**.If you want to talk about the study with someone who is not part of the study team, talk about your rights as a research participant, or to report problems or complaints about the study, contact the UW Human Subjects Division.

|  |  |
| --- | --- |
| **Study Team** | [Insert name(s) and contact info]  [If applicable, insert 24 hour contact number] |
| **UW Human Subjects Division** | 206.543.0098  [hsdinfo@uw.edu](mailto:hsdinfo@uw.edu) |

[If documentation of consent has not been waived by the IRB, include the appropriate signature line for the participant, LAR, or parent/guardian. If the research is greater than minimal risk, include the consent presenter statement.]

**Consent presenter statement**

By printing my name on this form, I am attesting that I have provided the participant [and/or their legally authorized representative (LAR)] with information about this study. The participant[/LAR] has been given sufficient time to consider participation and I have answered any questions they had. The participant[/LAR] indicated that they understand the nature of the study, including risks and benefits of participating.

Printed name of study staff obtaining consent Date

**Participant’s statement**

By signing this consent form, I confirm that the study has been explained to me and I volunteer to participate in the research. I have had a chance to ask questions. If I have questions later about the research or feel I have been harmed by participating in the study, I can contact a member of the research team or the UW Human Subjects Division using the information listed above. I will receive a copy of this consent form. [If relevant add this sentence] I give permission to the researchers to use my medical records as described in this form.

Printed name of participant Signature of participant Date

[Delete parent/guardian and LAR signature lines if they don’t apply.]

Printed name of parent/guardian Signature of parent/guardian Date

Printed name of legally authorized representative (LAR) Signature of LAR

Relationship of LAR to participant Date