|  |
| --- |
| **INSTRUCTIONS** (delete this text box once editing is complete)   * This template is intended for studies that are required to have a distinct [Key Information](https://www.washington.edu/research/hsd/guidance/consent/#5) section per UW IRB policy. These are studies that have consent forms with **more than 2,000 words**. * 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]

**Principal Investigator:** [insert name and contact information]

**Primary Participant Contact:** [if other than the PI, include name and contact information]

[If applicable, include 24 hour contact number.]

[Informed consent must begin with a concise and focused presentation of [Key Information](https://www.washington.edu/research/hsd/guidance/consent/#5) that is most likely to assist prospective participants, or their representatives, in understanding the reasons why they might or might not want to participate in the research. This template outlines the information that will often be included, but what constitutes Key Information is determined by the specific study population and procedures. The Key Information section should be shorter than the rest of the consent process/form.

When writing Key Information, consider the following questions from the perspective of the prospective participant:

* What are the main reasons they might choose to join, or not join, this study?
* What is the research question, why is it relevant to them, and in what ways is it novel?
* What aspects of participation are likely to be unfamiliar, diverge from expectations, or require special attention?
* What information is being collected, what activities (procedures) will they undergo, and what is the anticipated time commitment?
* What impact will participation have outside the research (e.g., will it reduce options for standard treatments) and how will research procedures differ from treatment they would receive as a patient outside the study?

Review the [Key Information Examples](https://www.washington.edu/research/forms-and-templates/example-key-info/) document which demonstrates several different approaches to presenting Key Information. The Key Information section should be 2 pages or less.]

Key Information about this study and what you will be asked to do.

We are conducting this study because [Insert a brief description of the purpose of the research]. You are being asked to participate because [insert eligibility criteria, as appropriate]. **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 the study is delivering a treatment, consider adding a statement that neither the decision to participate in the study nor a decision to withdraw from the study will adverselty affect their relationship with or treatment received from their healthcare provider(s).]

If you decide to be in this study, we will ask you to [Insert a description of the study procedures that would be most likely to influence the prospective participant’s decision about whether to enroll in the study. This should include a description of any investigational drug or device and its marketing authorization status and identification of any experimental procedures. If relevant to the propsective participants, include a description of the expected duration of participation. For studies with a big time commitment, consider including the number of visits and time duration per visit. A more complete description of the procedures and/or additional details about the procedures may be described later in the form. Consider providing a hyperlink or page reference to that section of the consent form.

Generally, information presented in the Key Information section does not need to be repeated elsewhere in the consent form. There may be some limited situations when intentional repetition of information could improve comprehension or clarify complex concepts (e.g., certain risks, alternatives, uncertainty about benefits). For example, it may improve comprehension to briefly describe the most serious or common reasonably foreseeable risks in the Key Information section and to repeat that information again, perhaps in greater detail, in the section of the consent form that includes a comprehensive description of reasonably foreseeable risks.

Consider using bulleted lists or tables rather than dense paragraphs to provide this information.].

* Procedure 1
* Procedure 2
* Procedure 3
* Procedure 4
* Procedure 5
* Procedure 6

| **Reasons you might say “yes” to being in the study.** | **Reasons you might say “no” to being in the study.** |
| --- | --- |
| [List the expected benefits to individual participants or society (if any) of participating in the research. If there is no, or unknown potential for direct benefit resulting from experimental treatments, this should be communicated. Known benefits should be accurately described and not exaggerated. For potential or uncertain benefits, describe clearly what is known about the uncertainty or likelihood of the benefits.  Financial reimbursement, incentives, and other payment participants will receive for participation is likely to be Key Information for most studies.] | [Desribe the most important reasonably foreseeable psychocological, social, economic, legal, physical, and/or privacy risks. If a full list of risks is provided later in the consent form, provide a hyperlink or page reference. If applicable, note that the research may involve currently unforeseeable risks. If applicable, note the possibility that participation may not improve, or could exacerbate a prospective participant’s condition.  Identifying the most important risks will depend on the particulars of the study and participant population. For example, for one study, the most important risks might be from a blood draw, so that should be listed in Key Information. However, for another study, a blood draw may be one of many procedures, some of which have much higher risk, in which case the blood draw would be omitted from Key Information.  This [guidance](https://www.washington.edu/research/hsd/guidance/consent/#r) provides information about how to assess which risks are reasonably foreseeable.  [If applicable, this may also be a place to describe reasons other than the study risks that participants may not want to participate. 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. For studies where participants may incur costs to participate, that might be a reason they don’t want to participate. It may be appropriate to briefly state whether compensation for research-related injury is available and then provide a page number or hyperlink to detailed information later in the consent form. The reasons a participant may not want to participate will be study- and population-specific.] |

Key Information about your options outside of this study.

[If applicable, describe alternatives to research participation that participants may wish to consider.]

[For research that includes medical treatment, the alternatives 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.

Key Information about how to ask questions.

**Read more about this study.** The next pages of this form give you more information about the study including [list the information that is explained in more detail outside the Key Information section].

**Talk to the study team.** We are here to help you understand the study. Please ask us any questions you 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 give you time to think about whether or not you want to sign up.

**Talk to someone else.** You may want to discuss your decision about whether to sign up with your family, friends, your regular doctor, or someone else. You can show them this document to help them talk about the study with you.

**Talk to someone about your rights as a participant.** 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 at [hsdinfo@uw.edu](mailto:hsdinfo@uw.edu) or 206.543.0098.

Additional information about research procedures.

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

[If the study procedures, any experimental procedures, and/or estimated duration of participation are not fully described in Key Information, provide more information here. If the research includes use of investigational drugs or devices, the consent form must describe the drug or device as experimental, investigational, unapproved or some other comparable term and note that the item is not FDA approved for clinical use or for this particular research use. For investigational device studies, it may be appropriate to describe whether the device will be removed at the end of the study, whether the device will be replaced if it removed for safety or other reasons, and if the device is subject to life-long tracking requirements.

The UW IRB encourages researchers to describe the procedures using bullets lists, tables, diagrams, or some other visual presentation rather than providing dense blocks of text. It may not be necessary to describe every procedure in detail. For example, rather than listing every instrument that participants will complete, it is sufficient to note that participants will complete several surveys/questionnaires and provide a brief summary of the general content. All experimental procedures must be described. 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 |

Additional potential benefits of the study.

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

[If the potential benefits to participants or othersare not fully described in Key Information, provide more information here.]

In addition to the benefits described at the beginning of the consent form, additional potential benefits include [insert description here].

Additional potential risks or side effects of the study.

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

[If the reasonably foreseeable risks and/or (if applicable) any unforeseeable risks are not fully described in Key Information, provide more information here. Careful consideration of “reasonably foreseeable” risks is particluarly important when there are risks associated with drugs, devices, or complex procedures. For investigational drug and device studies, the consent form should include the risk information in the investigator brochure. For device studies, the consent form should also describe the risks of implants and the possible need to remove them. For drug and device studies the consent form cannot include statements that claim investigational drugs or devices are safe or effective for the purposes of the investigation and cannot state that the FDA has given permission for or approved the clinical investigation. 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.

Depending on the study and potential risks, it might be more clear to describe the risks in a bulleted list, table, diagram, or other visual representation rather than a dense block of text. 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 addition to the risks described at the beginning of the consent form, additional risks include [insert description here].

How will we protect the information you provide?

[Review the guidance, [Designing the Consent Process](https://www.washington.edu/research/hsd/guidance/consent/design/#protect) 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 or other medical record]. This means people outside the research such as health insurers, health care providers, and anyone you have given permission 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?

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

[For some studies, such as drug and device studies, participants may need to be informed if significant new information arises during the course of the research that may impact their willingness to continue participation. It is particularly relevant for studies where knowledge of the risks is limited.] **While you are taking part in this study, we may learn new information** about [insert relevant information]. If this happens, we will contact you about the new information so you can decide if you want to stay in the study.

[For some studies, such as those with a treatment intervention or those that include an implanted device, participants may experience adverse health or welfare effects if they withdraw from the study without taking certain precautions. For some studies, there may be circumstances under which the research team may decide to terminate a participant’s participation due to risk, change in eligibility criteria, the DSMB recommending the study end early, or some other reason. Participants should be told about likely circumstances under which their participation may be terminated. The consent form should provide them with information about how to safely withdraw, in either circumstance.] **If you decide you want to stop being in this study**, be sure to contact the study team. If we discover that [insert reasons why a participant’s participation may be terminated] we can choose to end your participation in the study. If you stop participating and you are no longer receiving the study therapy, you may experience [describe any adverse health or welfare effects participants might experience]. We want to make sure you have the resources you need to be cared for outside of the research [insert details as appropriate].

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

[Review the guidance, [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 revise 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].)

[Inform participants if 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 repositories in de-identified format, include the language below. If sharing to non-NIH repositories, or when sharing in identifiable form, review the discussion in [Designing the Consent Process](https://www.washington.edu/research/hsd/guidance/consent/design/#genome) for instructions.]

**Sharing your information.** The National Institutes of Health (NIH) has developed data (information) banks that collect study data. The NIH will store your de-identified information in these data banks for other researchers to use in future studies on any topic. The researchers could be from government, academic, or commercial institutions.

[Include this language if data will be stored in an unrestricted access database] The information from this study will be stored in a public unrestricted data bank that anyone can use. This public information will not include your name or other information that could identify you.

[Include if participants will not receive results] You will not receive any results from allowing your data to be placed in the NIH data banks.

[Include if data can be withdrawn] You can withdraw your consent any time you don’t want your data in the NIH data banks. There will be no consequences for withdrawing consent. However, data that has already been sent to researchers cannot be retrieved.

[Include if data cannot be withdrawn] You will not be able to withdraw your information after it has been submitted to the NIH data banks.

[Include any applicable risks associated with broad sharing of the data. Note that this is not a complete list and other risks may need to be included. Delete any risks that do not apply to the type of data being shared. For example, if you’re not sharing genomic data, remove the risks that mention genes and genetic heritage.] Risks associated with sharing information data through NIH data banks include:

* It is possible that your information could be used to identify you when combined with information from other public sources.
* Others may be able to trace this information back to you or close biological relatives. The current risk of this happening is small but may grow in the future as new technologies are developed.
* If this should happen, someone might use this information to learn something about your health or genetic heritage. If linked to a medical condition and inappropriately shared with someone, it could affect your ability to get or keep some kinds of insurance.
* There is a possibility that this information could affect family members because certain conditions and traits run in families and are inherited through genes. This could hurt family or other relationships.
* There is a risk that your information could become known to the public, employers, or law enforcement agencies. The information may be used to enforce negative stereotypes.
* There may be other risks that are not yet known.

[Include this language when sharing of data will be optional (i.e., not a condition of participating in the research). Note that it is best to place checkboxes at the end of the consent form to ensure they aren’t missed.] It is your choice whether or not to have your information placed in NIH data banks for use research in the future. If you say “No,” you can still fully participate in this study. Do you agree to have your information shared through NIH data banks?

**Yes**, I consent to having my information placed in NIH data banks for future research use.

**No**, I do not consent to having my information placed in NIH data banks for future research use.

[Include this language if participants will be given the option of receiving results of medical importance. Note that it is best to place checkboxes at the end of the consent form to ensure they aren’t missed.] In general, you will not receive any individual results from future research conducted with information placed in the NIH data banks, but in rare circumstances researchers may find something that may be of medical importance. If this happens, do you want to receive these results?

**Yes**, I consent to receiving results if researchers find something of medical importance.

**No**, I do not consent to receiving results if researchers find something of medical importance.

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

[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].

[If participants may incur costs as a result of research participation, they should be informed. For device studies, this may include the costs for implantation and removal, training the patient about how to use and monitor the device, and any required maintenance or repairs on the device. It is important to distinguish research procedure costs from clinical care costs. Understanding what may or may not be paid for by medical insurance can be complex and it may be appropriate to refer the participant to a financial counselor. This example language is **required** if the research is a clinical trial that involves the use of clincial services, items, or tests and there may be costs to study participants or their insurers. If costs were fully described in Key Information, do not repeat that information here.] **The costs of the experimental [drug/device] and/or the costs of the treatment procedures may be billed to you, or your health insurance** as would normally be the case for clincial care. In some cases, your health insurance company may not pay for costs associated with a research study. You can talk with the research team and/or contact your health insurance company directly to identify what will and will not be covered.

[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.] 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].

[For **greater than minimal risk** studies not funded by an industry sponsor and for which the procedures associated with the risks are performed by a UW agent, insert one of the two statements listed below describing the UW discretionary Human Subjects Assistance Program (HSAP). **This language cannot be altered.**]

([For studies *with medical risks*.]The costs of the treatment may be billed to you or your health insurance [for international studies, refer to national health insurance or health service or program] just like other medical costs, or it may be covered by the UW’s discretionary Human Subjects Assistance Program (HSAP), depending on a number of factors. The researcher may request HSAP coverage by following established procedures. If you wish to request HSAP coverage yourself, contact the researcher or the UW Human Subjects Division at [hsdinfo@uw.edu](mailto:hsdinfo@uw.edu) or 206-543-0098. Ask the researcher if you would like information about the limits and conditions of the HSAP. The UW does not normally provide any other form of compensation for injury. However, the law may allow you to seek payment for injury-related expenses if they are caused by malpractice or the fault of the researchers. You do not waive any right to seek payment by signing this consent form. [If appropriate, also add these two sentences] We will bill your health insurance for treating problems that result from your [insert name of disease or underlying condition] or from standard clinical care. If you have no health insurance or your insurance refuses to pay, we will bill you.)

([For studies *without medical risks*.] The UW does not normally provide compensation for harm except through its discretionary program for medical injury. However, the law may allow you to seek other compensation if the harm is the fault of the researchers. You do not waive any rights to seek payment by signing this form.)

[If participants will receive payment 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 payment information was fully described in the Key Information section, do not repeat that information here.]

[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.

[For some studies, such as a drug or device trials, a participant’s decision about whether to participate may be impacted by the number of participants in the study. Below are some example statements that could be included.] (**We plan to enroll [insert number] people** in this study.) **[OR]** (There are [insert number] sites in this study across the U.S. We plan to enroll [insert number] people at the UW site.)

[If the UW has issued a Financial Conflict Management Plan, include this language. For non-UW investigators, review the guidance on [Designing the Consent Process](https://www.washington.edu/research/hsd/guidance/consent/design/#fcoi).] **[Investigator name] has a financial or other relationship with [company name].** The University of Washington developed a Conflict Management Plan to reduce the possible effects of this relationship on your safety or welfare.

[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.

[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 partent/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