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| University of Washington Human Subjects DIvision | **GUIDANCE Consent Elements for** **Externally Reviewed Studies**  |

**PURPOSE and APPLICABILITY**

The University of Washington has no institutional requirements for the format of consent materials and strongly supports flexibility for consent format and content. UW researchers obtaining review from an external IRB should follow the general policies and guidance of the external IRB for general content and format. In the absence of guidance from the external IRB, the [UW consent templates](https://www.washington.edu/research/hsd/guidance/consent/templates/) provide general sample language and suggested organization, but these are not required, except as described below. For studies reviewed by an external IRB, it is typically most efficient to add the UW required elements to the sponsor or external IRB’s template consent forms. The UW study team is responsible for ensuring that any applicable elements are included in the consent materials reviewed by the external IRB.

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| **REQUIRED ELEMENTS** |  |  |
| **Consent Element** | **When is it required?** | **Required Consent Language (as written unless otherwise indicated)** |
| The University of Washington named on the title page. | **Required When:**UW is the only institution involved, or when UW is one of the sites in a multi-site study where each site is conducting the protocol.**Explanation:**Required by UW HSD policy in order to help subjects identify the organization responsible for the conduct of the research. | University of Washington |
| The source of any external (i.e., non-UW) sources of funding or support for the research. | **Required When:**There is any non-UW funding or support for UW’s activities. **Explanation:**Required by UW HSD policy in order to inform subjects who is paying for the study.Some device clinical trials approved prior to 2015 may have a letter from the FDA specifying particular required consent language. This language cannot be edited. | *Alternative language that conveys the same meaning may be used.*The study team and/or the University of Washington is receiving [financial support OR describe other type of support such as “the study drug”] from [insert sponsor’s name]. |
| A description of any financial conflicts of interest. | **Required When:**Any UW investigator (as defined by UW policy [GIM 10](https://www.washington.edu/research/policies/gim-10/)) has a Financial Conflict of Interest related to this study, as defined by UW policy GIM 10.**Explanation:**Required by UW’s Financial Conflict of Interest policy and the stipulations of individual management plans issued to investigators. | *Alternative language that conveys the same meaning may be used.*[Investigator name] has a financial or other relationship with [company name]. The University of Washington (UW) developed a Conflict Management Plan to reduce the possible effects of this relationship on your safety or welfare. |
| Information about fetal tissue from elective abortions. | **Required When:** The portion of the research involving UW will collect fetal tissue donated from elective abortions. **Explanation:** Required in order to meet expectations of NIH NOT-OD-19-128 & NOT-OD-19-137. UW applies this requirement to all research regardless of funding. | We will obtain your consent to donate fetal tissue only after you have already provided written consent to have an abortion. Your research consent will not be obtained by the same person who obtained your abortion consent. Being in this research will not affect the method used for your abortion. No payment, other financial benefits, gifts, or incentives can be provided to you for having an abortion or for donating the tissue for research. |
| Information about potential study costs for subjects in clinical trials. | **Required When:**The research is a clinical trial that involves the use of clinical services, items, or tests through UW Medicine or UW Physicians (UWP) and there may be costs to study subjects or their insurers. **Explanation:** Some insurance, like WA State’s Apple Health (Medicaid), have explicit rules about billing for clinical trial costs. This language has been developed to ensure study subjects are aware of any additional costs that may result from their participation in the research. | *Alternative language that conveys the same meaning may be used.*The cost of the experimental drug/device and/or the costs of some research procedures may be billed to you or your health insurance as would normally be the case for clinical 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. |
| That information about study participation will be placed in the subject’s medical record. | **Required When:**The research is any study that involves the use of clinical services, items, or tests through UW Medicine or UW Physicians (UWP). This includes most uses of the UW Translational Research Unit (TRU).**Explanation:**When these services are used, study participation is noted in the subject’s medical record which can be seen by anyone who accesses the record. This note is made for patient safety and to facilitate billing under The Medicare Clinical Trials Policy (CTP).Subjects should be informed about this note, and any other information placed in the record, in order to meet the required consent element at §46.116(a)(5): *A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.* | *Alternative language that conveys the same meaning may be used.*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 a consent form will be placed in the medical record] A copy of the consent form for this study will be placed in your medical record. |
| The following information must be provided to subjects in writing, prior to the signature, to facilitate e-consent:* A statement that a copy of the consent information (e.g., consent form) will be provided electronically, including a description of the hardware and software requirements necessary to access/read the document;
* How a subject can request and receive a paper copy of the consent form and whether there is a cost;
* How a subject can withdraw consent (for example, by contacting the researcher, including a description of how)
 | **Required When:**Using an electronic signature process to document consent when written documentation of consent has not been waived by the IRB. **NOTE:** UW HSD must concur with the use of e-signature platforms on a study-by-study basis in order to make sure that the platform is acceptable under UW policy and WA state requirements. The reviewing IRB must also approve its use.**Explanation:** These elements are required by the federal ESIGN Act, which UW and Washington State follow. It is preferred that this information is described in the consent form/documents presented to subjects but may be presented as part of the system functions (e.g., pop-ups) as long as the information is provided *prior* to consent.  | **How to present the required information.** The UW’s guidance on [**Designing the Consent Process**](https://www.washington.edu/research/hsd/guidance/consent/design/econsent) has example language.If there is a UW-specific consent form, the information should be provided in the consent form. If there is no UW-specific consent form, the information can be provided in any format that is * in writing, and
* is provided prior to the signature, and
* that can be printed, accessed again at a later date, or otherwise retained.

**Below is example language that may be used with ITHS REDCap.**For other e-consent systems, check with the system owner to understand how the system will meet the requirement and provide that information during consent.*Alternative language that conveys the same meaning may be used.*A copy of the consent form will be emailed to you at an email address that you provide. 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 [insert instructions for how to obtain a copy]. If you wish to withdraw from the study, please [insert instructions for who to contact/how to withdraw]. |
| A description of any Federal Certificate of Confidentiality (CoC). | **Required When:**The study is NIH and/or CDC funded, **or** the study has applied for and received a CoC. **Explanation:**Issuers of CoCs expect that the researcher will tell participants about the protections afforded by the CoC and any exceptions to that protection. | *Alternative language that meets* [*NIH’s expectations*](https://humansubjects.nih.gov/coc/suggested-consent-language) *for a description of the CoC may be used.*We have a Certificate of Confidentiality from the U.S. federal [insert institution, e.g., National Institutes of Health] which allows us to keep your identifiable research information confidential 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 subject’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. |
| Standard language about ClinicalTrials.gov. | **Required When:**The study is required to be listed in the federal clinical trials registry at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) by the FDA, NIH, or another regulatory agency.**Explanation:**These agencies expect that the researchers will tell subjects about the registry. | [This language is required per federal law and cannot be modified]A description of this clinical trial will be available on <https://www.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 studies *not* funded and initiated by an industry sponsor:**A statement about the [availability](https://www.washington.edu/research/policies/human-subjects-assistance-program-2/) of medical treatment and other compensation for injury. | **Required When:**All of the following apply:* the reviewing IRB determines that the study poses greater than minimal risk to subjects\*
* the procedures associated with the risks are performed by a UW employee, student, or agent
* the study is not funded and initiated by an industry sponsor
* There is no alternative process and/or language required by a component of the federal Department of Defense

**Explanation:**The [UW Human Subjects Assistance Program (HSAP)](https://www.washington.edu/research/policies/human-subjects-assistance-program-2/) is a discretionary program that may provide limited medical and other assistance to subjects who experience a research-related medical problem that is more likely than not caused by UW-conducted research.One of the two language alternatives should be included in the consent document in order to meet the required consent element at 45 CFR 46.116(a)(6): *For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained.* \***For research that is no greater than minimal risk**, we **strongly encourage** study teams to identify whether there are medical risks involved and to include the associated appropriate UW specific language in the consent form. | **[For UW studies involving 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 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**.**[Ifappropriate, also add] 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 UW studies involving no 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 right to seek payment by signing this consent form. |
| **For studies *that are* funded and initiated by an industry sponsor:**A statement about the availability of medical treatment and other compensation for injury. | **Required When:**All of the following apply:* the reviewing IRB determines that the study poses greater than minimal risk to subjects
* the study is funded and initiated by an industry sponsor

**Explanation:**In order to meet the required consent element at 21 CFR 50.25(a)(6): *For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.* | *As of February 28th, 2025: For research under a single study CTA executed after January 1st, 2025, HSD strongly recommends using the following stock language, which will become mandatory at some time in 2025. Until this language is mandatory, alternative language that conveys the same meaning may be used.*The sponsor, [INSERT NAME OF COMPANY], will be responsible for your reasonable and necessary medical costs for treatment for a research-related illness or injury if the injury or illness:• is a direct result of the [drug/device/intervention] being studied or the properly performed study procedures• is not a medical condition that you had when you started the study;• is not the direct result of a failure to follow the study plan; and• is not the direct result of proven negligence of University of Washington. Talk to the study team about how this payment will be made. The sponsor does not plan to provide any other form of compensation to you for any illness or injury resulting from this study. University of Washington does not plan to provide free medical care or payment for treatment of any illness or injury resulting from this study unless it is the direct result of proven negligence by a University employee.*For research under an MCTA and any other research: Use language supplied by the sponsor and modify as needed to avoid violating MSP (see below).***Language that does not violate MSP and can be used if the contract states that subjects’ insurance will be charged. For example**If you do not have health care coverage or insurance, or if your coverage is provided by a federally-funded governmental program such as Medicare, Medicaid, or Tricare, the sponsor will pay for the cost of treating your illness or injury. If you have private health coverage, your insurer will be billed for the treatment.**OR**If you sustain physical illness or injury as a result of the study drug, the sponsor will reimburse the institution for the costs of your medical treatment for this physical illness or injury. This reimbursement will only be made for costs not covered by your own third-party non-governmental insurance.**The following examples *violate* MSP and are not allowed:*****The sponsor of the study will pay (or reimburse) for the treatment of illness or injury caused by the study drug to the extent such treatment is not paid by your insurer.******Your insurance company or you will be billed for the treatment of illness or injury caused by the study drug, but if your insurance refuses to pay, the sponsor will pay.*** |
| **For studies in which subjects are likely to earn $600 or more at UW site(s) during the calendar year:**A statement that the University is required to report subject payments of $600 or more as miscellaneous income to the IRS. | **Explanation:****Required When:**Subjects are likely to earn $600 or more at UW site(s) during the calendar year.**Explanation:**The UW Financial Management office is responsible for reporting to the IRS, instances when a subject receives an aggregate total of $600 or more in UW research subject payments.  | *Alternative language that conveys the same meaning can be used:*If you earn $600 or more in subject payments from the University of Washington during this calendar year, the UW will report this to the Internal Revenue Service as Miscellaneous Income. |

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| Standalone HIPAA Authorization required for accessing UW Medicine and/or Fred Hutch records. | **Required When:** Researchers are accessing UW Medicine and/or Fred Hutch records with patient permission. **Explanation:** Washington State law requires explicit “opt in” language for release of certain types of health care information as well as other unique requirements. UW Medicine and Fred Hutch have vetted [a stand-alone form](https://www.washington.edu/research/forms-and-templates/template-hipaa-authorization/) for compliance with HIPAA as well as other laws and policies applicable to the use of UW Medicine and Fred Hutch PHI. Elements of HIPAA Authorization language contained in consent forms may not meet these requirements and UW does not rely on external IRBs or sponsors to vet language for compliance with HIPAA or these laws and policies. For some studies reviewed by the Fred Hutch IRB, HIPAA language embedded in a consent form may be acceptable in lieu of a standalone form. Work with the Fred Hutch IRB to understand these situations. | **Use these templates:** [UW HIPAA Authorization template](https://www.washington.edu/research/forms-and-templates/template-hipaa-authorization/) [UW HIPAA Authorization template for pregnancy](https://www.washington.edu/research/forms-and-templates/template-hipaa-authorization-pregnant-partner/)Language in these templates cannot be modified. UW HSD does not require that the non-UW IRB review the HIPAA Authorization template as part of its review. Researchers should follow the instructions of the non-UW IRB about whether to include the HIPAA Authorization form in their submission to the IRB.**Include the following statement in the consent form** (a*lternative language that conveys the same meaning can be used):* You will be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) Authorization form authorizing access, use, creation, or disclosure of health information about you.*Note about consent templates that already include HIPAA language:* Occasionally, sponsors and non-UW IRBs have already included HIPAA language in consent forms. If it can be reasonably accomplished, this information should be removed from the form. If it cannot be removed, for example the sponsor rejects the request, or the study team cannot identify which elements are HIPAA specific, the UW study team should compare the consent form to the HIPAA Authorization form to ensure that the information in the two forms is not in conflict. Contradictory information in the consent form must be removed or revised for consistency with the UW/FH HIPAA Authorization form. |

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| **ELEMENTS NOT ALLOWED** |  |  |
| **Type of language** | **Why is it not allowed?** | **Examples of prohibited language** |
| Statements that only the research team will have access to the data or specimens. | This cannot be guaranteed, because of the many possible secondary uses of data and the many organizations and offices (UW or otherwise) that have the right to monitor or audit the study in its entirety. | “No one outside of the study team will see your study data or know your name.”“We will never share your results with anyone outside of the study team.” |
| Guarantees to pay for treatment or diagnosis of any illness or injury, **unless the study is industry-sponsored and the contract expressly describes this payment, or the Department of Defense or a DoD component is providing treatment.** | Guarantees or promises cannot be made on behalf of the UW. The [UW Human Subjects Assistance Program (HSAP)](https://www.washington.edu/research/policies/human-subjects-assistance-program-2/) is a *discretionary*, no-fault program that *may* provide medical and other assistance to some subjects. Payment cannot be guaranteed.Additionally, such guarantees to pay trigger the [Medicare Secondary Payer (MSP)](https://www.cms.gov/Medicare/Coordination-of-Benefits-and-Recovery/Coordination-of-Benefits-and-Recovery-Overview/Medicare-Secondary-Payer/Medicare-Secondary-Payer.html) rule which states that Medicare does not have primary payment responsibility when another entity has promised to pay. If the consent form guarantees payment for treatment or illness or injury by another entity, Medicare cannot be charged for the treatment. | “You will not have to pay for any emergency care expenses that are directly related to conditions caused by the study.”“The study will pay for treatment of any injury you receive from participation.” “The sponsor of the study will pay (or reimburse) for the treatment of illness or injury caused by the study drug to the extent such treatment is not paid by your insurer.”“Your insurance company or you will be billed for the treatment of illness or injury caused by the study drug, but if your insurance refuses to pay, the sponsor will pay.” |
| Statements that the University will not provide compensation in case of a research related injury.  | The [UW Human Subjects Assistance Program (HSAP)](https://www.washington.edu/research/policies/human-subjects-assistance-program-2/) is a discretionary program that may provide limited medical and other assistance to subjects who experience a research-related medical problem that is more likely than not caused by UW-conducted research. Blanket statements that compensation will not be provided are inaccurate. | “The study site does not provide funds for the treatment of research-related injury.”“In the event that the participant suffers injury as a result of their participation in this research study, no compensation will be provided to the participant by the granting agency, the treating institution, or the researchers.” |

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| **OPTIONAL ELEMENTS** |  |  |
| **Type of language** | **When might you want to include it?** | **Example language** |
| Information about genomic data sharing. | When genomic data will be submitted to NIH designated repositories and HSD will certify the data for submission under NIH’s [Genomic Data Sharing policy](https://www.washington.edu/research/hsd/guidance/ancillary/gds/). This language also satisfies consent requirements for submissions of non-genomic data under [NIH’s Data Management and Sharing Policy.](https://sharing.nih.gov/data-management-and-sharing-policy) **Explanation:**NIH expects that appropriate consent that meets each institution’s certification requirements will be obtained from subjects. HSD’s consent language has been developed in order to facilitate certification under HSD’s [Genomic Data Sharing policy](https://www.washington.edu/research/hsd/guidance/ancillary/gds/).**When another institution will certify the data**, you may *choose* to use HSD’s language, but check to make sure that the language meets that intuition’s certification requirements. | *Alternative language may be used. This example language is designed to obtain broad consent for future uses and sharing of genomic and phenotypic data. However, sometimes tiered or specific consent approaches may be more appropriate. For example, the consent form could limit use of data to the study of specific diseases or conditions.* 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.]** Risks associated with sharing information 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 to 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)]**It is your choice whether or not to have your information placed in NIH data banks for use in future research. 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, my information can be placed in NIH data banks for future research.[ ]  No, my information cannot be placed in NIH data banks for future research.**[Include this language if participants will be given the option of receiving results]**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 want to receive results that may be medically important.[ ]  No, I do not want to receive results that may be medically important. |
| Contact information for the UW Human Subjects Division (HSD). | In order to meet the requirement that subjects be told whom they can contact for questions about their rights as a participant in a research study or if they have a concern about the study that they cannot address with the local study team. However, in most cases, the reviewing IRB’s contact information should be provided rather than, or in addition to HSD’s.  | If you have questions about your rights as a study participant, you can contact the University of Washington Human Subjects Division hsdinfo@uw.edu or at (206) 543-0098. |

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| **Version Number** | **Posted Date** | **Implementation Date** | **Summary of Changes** |
| 2.8 | 05.01.2025 | 05.01.2025 | Updates to instructions about HIPAA language. |
| 2.7 | 03.27.2025 | 03.27.2025 | Updates to compensation for injury  |
| 2.6 | 01.30.2025 | 01.30.2025 | Minor revisions to costs language; allow alternative language for some elements  |
|  2.5  | 08.29.2024 | 08.29.2024 | Add instructions for minimal risk injury language and disallowing statements that no compensation is available |
| 2.4 | 05.30.2024 | 05.30.2024 | Clarify that HSAP language should be included unless study is funded *and initiated* by industry sponsor |
| 2.3 | 01.04.2024 | 01.04.2024 | Clarify HIPAA language |
| 2.2 | 06.01.2023 | 06.01.2023 | Add references to new consent template language and guidance |
| Previous versions |  |  | For older versions: HSD staff see the SharePoint Document Library; Others – contact hsdinfo@uw.edu. |

**Keywords:** Consent; External reliance; Multi-site