TIP SHEET Consent: A Meaningful Consent Process

Facilitating Informed Decision-Making

(Details: **GUIDANCE Consent** *Consent Overview*)

Research consent must be designed from the perspective of the subject population to ensure informed decision-making.

What information is provided

Emphasize the Key Information that would be *most likely to influence the subject's decision to participate*.

It is not necessary to describe every procedure a subject will undergo at the time of the consent interaction.

After enrollment, the consent process can be supplemented with a detailed timeline of procedures or other information.

How information is provided

Presentation of consent information must *facilitate comprehension*.

- Provide information in a logical sequence that allows for real-time discussion between subject and study staff.
- Communicate using language that is familiar and at an appropriate reading level.
- Simplify complex information by using shorter words and sentences.
- Avoid medical or technical jargon.
- Speak and write in an active voice and conversational style. (e.g., *passive* "A drug will be given." versus *active* "You will be given a drug.")

Consider the *perspective of the subject population*.

- The information provided should describe the pros and cons of enrolling in the research for those particular subjects.
- Describe what participation means for those particular subjects. For example, if subjects will be randomized, tell subjects what that means *for them*:
  - they cannot choose the group they're in;
  - they will not be assigned to a group based on what is best for them;
  - if they prefer to be in a certain group, they may not want to participate.

The Consent Process

(Details: **GUIDANCE Consent** *Consent Overview*)

Consent is a continuous, dynamic, and interactive process. The process usually begins with the information presented in recruitment materials, includes the consent interaction, and continues in post-enrollment communications. Subjects consider throughout a study whether they wish to continue participation.

Allow adequate time for subjects to consider participation.

Allow adequate time while the researcher reviews the consent form with subjects.

Give subjects the option to take some time between reviewing the consent form with the researcher and actually providing consent for participation. Going home to think about it, talking with family and friends, or consulting with their personal physician all may help subjects make a decision.

This is particularly important for complex studies, high-risk studies, protected or vulnerable populations, and other groups that may experience a comprehension barrier (e.g., subjects with visual impairments; subjects with limited English proficiency).

Key Information (Details: **GUIDANCE Consent** *Key Information* and **EXAMPLE Key Information**)

The consent process must begin with a concise and focused presentation the Key Information that a reasonable person would want to know in order to make a decision about whether to participate in research. A separate Key Information section is only required if the consent form has more than 2,000 words.

To identify Key Information, ask :

- What are the main reasons a subject would, or would not, want to enroll?
- What is the research question and why might it be relevant for the subject?
- What information about the subject will be collected? What activities (procedures) will the subject be asked to do?
- How will their experience as a research subject in this study differ from treatment they might receive as a patient outside of the study?
- What aspects of the study are likely to be unfamiliar, diverge from expectations or require special attention? (e.g., "Being in this study means you will have to come to the clinic more often than you regularly do.")

TIP SHEET Consent: Written Consent Materials

Written Consent Materials (Details: **GUIDANCE Consent** *Consent Considerations*)

Written consent materials should be designed as teaching tools that provide information in a thoughtful, meaningful way rather than serving as a checklist of regulatory requirements. The regulations do require certain characteristics and elements of consent to be present, but researcher have flexibility in how to satisfy these requirements.

The **WORKSHEET Consent Requirements and Waivers** lists: characteristics of consent; elements of consent; funding agency requirements; protected population requirements; HSD requirements; and waiver criteria.

Structure and Format

The consent form must begin with a concise and focused presentation the **Key Information** (**GUIDANCE Consent** *Key Information*) that a reasonable person would want to know in order to make a decision about whether to participate in research.

- A separate Key Information section is required for consent documents greater than 2000 words. Otherwise, the consent form is considered to meet the requirements of being "concise and focused".
- Use the valuable "real estate" of the first page of the consent form to provide information subjects are most interested in (i.e., Key Information) rather than administrative details about the study (e.g., researcher titles and funding information).

Make headings **subject-focused** rather than serving as a regulatory checklist.

- Why might I want to participate?
- Why might I not want to participate?
- How will information about me be kept confidential?
- Who can answer my questions about the study?

Consider **alternatives to dense blocks of text**.

- Present information in side-by-side comparison tables (e.g., pros/cons of participation).
- Use diagrams or flow-charts to demonstrate the different steps or phases of participation.
- Use icons or color to emphasize particular topics.

Waiver of Documented Consent

(Details: **GUIDANCE Consent** *Documentation of Consent*)

Most minimal risk studies will qualify for a waiver of documentation of consent which allows for greater flexibility in the consent process and form. (Waiver criteria: **WORKSHEET Consent Requirements and Waivers**)

If documentation of consent has been waived by the IRB, an oral consent process may be appropriate (i.e., there is no written form provided to subjects). Or subjects may be provided with consent information using an information statement which does not require any signatures.

Documented Consent

(Details: **GUIDANCE Consent** *Documentation of Consent*)

If consent documentation cannot be waived:

- The subject, legally authorized representative, or parent/guardian must sign and date the IRB-approved consent form and receive a copy of the consent form .
- The researcher must print their name and date the consent form.
- In some circumstances, a witness signature may be required (e.g., if using short form consent).
- The signature may be hand-written, electronic, or in some other format, as approved by the IRB.
- If obtaining an e-signature, **UW ITHS REDCap** and **UW eSignatures (DocuSign)** have been vetted by the UW as meeting the federal and Washington State definitions of a "legally valid" electronic signature. (Details: **GUIDANCE Electronic Consent Signatures**, **GUIDANCE Consent** *Electronic Signatures;* TUTORIAL **Electronic Consent: What you Need to Know**)

TIP SHEET Consent: Population-Specific Considerations

Vulnerable Populations and Consent (Details: **GUIDANCE Consent** *Protected and Vulnerable Populations*)

When prospective subjects are at risk of being unduly influenced or coerced to participate in research, or have diminished capacity to consent, additional safeguards must be considered to ensure consent comprehension and protect subject autonomy and voluntary participation.

Some of the best tools for minimizing , or appropriately managing, the possibility of undue influence or coercion are to:

- Conduct a consent process that allows subjects adequate time to consider participation and have their questions answered.
- Ensure the consent process and materials include Key Information that is relevant to the subject population and in sufficient detail.

Subjects with diminished or fluctuating consent capacity (Details: **GUIDANCE Consent** *Diminished or Fluctuating Consent Capacity and use of LAR*)

- see **TIP SHEET Consent: Assent and Legally Authorized Representative**

Subjects with comprehension barriers or who cannot write or speak (Details: **GUIDANCE Consent** *Subjects with Comprehension Barriers*)

Consent information must be presented in a language that is understandable to subjects.

Translation, interpretation, or other accommodations may need to be provided and remain available throughout the subject's participation in the research.

Researchers should carefully consider the purpose of the research and the scientific question when considering the inclusion and exclusion of these subject populations, especially when the study may offer significant benefit to the individual subjects or subject population.

The *short form consent process* may be appropriate for the occasional and unexpected enrollment of non-English speaking subjects when there is no translated consent form and there is insufficient time and opportunity to obtain a written translation.

If possible, an electronic copy of the consent form that can be used with a screen reader should be provided to visually impaired subjects.

Protected Populations (Details: **GUIDANCE Consent** Protected and *Vulnerable Populations*)

Research with children requires obtaining permission from a parent or guardian and assent from the child. Permission may be required from one parent, both parents, or it may be waived or altered by the IRB. Documentation of permission may also be waived by the IRB.

WORKSHEET Children **TIP SHEET Consent: Assent & Legally Authorized Representative**

Research with pregnant women and neonates may require the consent of only the pregnant woman or of the pregnant woman and the father. Information about the reasonably foreseeable impact of the research on the fetus or neonate must be included in the consent process.

WORKSHEET Pregnant Women **WORKSHEET Neonates**

Prisoners participating in research must be informed in advance that participation in the research will have no effect on their parole or early release. Allowing adequate time for consideration and discussion of the consent process is particularly important for prisoner populations. The consent process must provide a clear and accurate description of confidentiality protections, given the institutional limitations that may exist.

WORKSHEET Prisoners **GUIDANCE Prisoners**

TIP SHEET Consent: Assent & Legally Authorized Representative

Subjects with Diminished or Fluctuating Consent Capacity (Details: **GUIDANCE Consent** *Diminished or Fluctuating Consent Capacity and Use of LAR*)

It may sometimes be appropriate for a **legally authorized representative (LAR)** to provide consent on behalf of a subject with diminished decision-making capacity. These impairments may be permanent, temporary, progressive, or fluctuating and the plan for consenting these populations will depend on these particulars.

Assent from these subjects should also be sought unless the subject is incapable of providing it or it is otherwise inappropriate to obtain assent.

Researchers are responsible for:

- Assessing for impaired consent capacity in the subject population, including changes over time.
- Describing in the IRB Protocol the process for determining consent capacity.
- Assessing whether the need to obtain LAR consent is a likely possibility.
- Assessing whether subjects are capable of providing assent and/or whether it is appropriate.
- Describing in the IRB Protocol the process for obtaining standard consent from a subject if they re-gain the capacity to consent during participation.

Assent (Details: **GUIDANCE Consent** *Protected and Vulnerable Populations*)

Assent is a subject's affirmative agreement to participate in research. Failure to object should not be equated with an active willingness to participate. It is **HSD policy** that assent must be obtained from children or adults with diminished decision-making capacity when the individuals are capable of providing assent and it is appropriate.

There are no regulatory requirements for particular elements, or for documentation of assent. It is up to the IRB to determine whether the researcher's proposal for assent is appropriate.

Researchers and the IRB must first determine whether subjects are capable of providing assent and then design an assent process (and form) that is appropriate for subject group's capacity to understand the research and their experience if they participate.

Generally, a subject's dissent should be respected, with some exceptions outlined in the **GUIDANCE Consent** *Protected and Vulnerable Populations*.

Child Assent (Details: **GUIDANCE Consent** *Protected and Vulnerable Populations*)

The assent process/form should take into account:

- The nature of the research.
- The age, maturity, psychological state of the children.

The content of the assent processes/forms will differ depending on the age of the children:

- **Younger children.** Assent processes/forms should focus on the aspects of the research that the children would be mostly likely to understand and be interested in.
    - Why is the research being done? What will they do? How long will it take? Will there be pain or discomfort? Will they be paid, or receive a gift for participating?
- **Adolescents.** Assent processes/forms may be similar to those designed for adults. It might make sense to use a single form to obtain parental permission and adolescent assent.

Just like consent, *assent is a continuous, dynamic, and interactive process.*

- A child enrolled in longitudinal research may need to be re-assented as their capacity to understand increases.
- If the child reaches the legal age of consent while enrolled, adult consent must be obtained for any ongoing interactions, interventions, or continued analysis of identifiable specimens or data, unless the IRB has granted a waiver of consent.

TIP SHEET Consent: Reconsent and Ongoing Subject Communication

Reconsent and Ongoing Subject Communication (Details: **GUIDANCE Consent** *Reconsent*)

Subjects may need to be informed of new information or consent may need to be revisited due to fluctuating consent capacity or because a child subject has reached the age of majority (See: **TIPSHEET Consent** *Assent and Legally Authorized Representative*). In these situations, it is important for subjects to be able to reaffirm their willingness to participate in research.

Verbal Discussion

This method may be appropriate for information that: **(1)** is simple; **(2)** does not change risks or benefits; and/or **(3)** is not likely to affect subject willingness to participate.

Examples

- Eliminating certain procedures from study visit
- Payment method being changed from cash to gift card

Letter or Email

This method may be appropriate when the information: **(1)** is easy to understand; **(2)** is not likely to affect willingness to participate; and/or **(3)** is important for subjects to have in writing for future reference.

Examples

- A new questionnaire is added that does not change the type or scope of questions already being asked
- Informing subjects of a new principal investigator
- Informing subjects they can use a commercial lab for blood draws

Providing Materials to the IRB

When new or revised information is reported to the IRB as a Modification or Report of New Information (RNI) in *Zipline*, researchers are prompted to consider whether subjects need to be informed about the changes.

Researchers must provide a description of the method and process by which subjects will be informed about the new information (e.g., in the section of the IRB Protocol titled, *Ongoing process, new information, and reconsent*; in correspondence; in the SUPPLEMENT RNI).

In addition, researcher should upload in *Zipline*:

- The text of any written correspondence that will be sent to subjects
- Any consent addendum(a)
- Any revised consent form(s)

Addendum

This method may be appropriate when information: **(1)** is complicated or important; **(2)** may impact willingness to participate; and/or **(3)** consent for the new information is required but does not rise to the level of requiring review of the entire study with a full reconsent.

Examples

- New measures being added include sensitive mental health topics subjects did not previously consent to
- New genetic analysis is added to samples already being collected for the study
- New risks are identified or there is an increase in frequency or magnitude of previously described risks
- A decrease in anticipated benefits is identified
- New/alternative therapies are identified

Reconsent

This method requires the most time and effort. It is appropriate when: **(1)** there is no time sensitivity; **(2)** the information is complicated; and/or **(3)** the information affects many aspects of the study.

Examples

- Subjects are moving into a new study phase with very different procedures
- Many changes are being made to the study
- A child subject reaches the age of majority
- Changes in cognitive functioning or mental/physical health now allow the subject to replace LAR consent with consent on their own behalf
- There is a significant delay between the initial consent process and the start of the study
- A consent refresher may be needed during a longitudinal study
- There are concerns about the way consent was obtained (e.g., wrong version of consent form was used; study staff were not properly trained)

TIP SHEET Consent: The IRB Approval Process

Regulatory Oversight (Details: **GUIDANCE Consent** *Regulatory Oversight*)

All UW research must comply with the Common Rule characteristics and elements of consent. Other agencies (e.g., FDA, DOJ, DOD) will have additional requirements that apply when the study receives funding or support from them.

Local laws in the jurisdiction where the research will occur, and institutional policies may also shape the consent process and document.

Researchers are responsible for identifying applicable state or other local laws when the research is conducted outside of Washington state, including internationally.

GUIDANCE Human Subjects Regulations **WORKSHEET Consent Requirements and Waivers**

Prior IRB Approval

All consent processes and materials must be approved by the IRB prior to enrolling subjects. This is true for new consent processes/forms as well as for any modification to existing processes/forms.

What to Submit

Procedures for obtaining consent and, if applicable, documenting consent must be described in the IRB Protocol. This includes procedures for screening and recruitment.

All written and oral consent materials must be submitted as part of the *Zipline* application

Guidelines about which recruitment materials must be submitted and which can simply be described in the application are provided in the IRB Protocol.

Translated version of all consent materials that will be provided to subjects in written form must be approved by the IRB before using them with subjects.

Translated versions should be submitted for any English recruitment materials that are required to be submitted as part of the application.

Translations should be provided to the IRB *after* the English versions are approved, either as part of the initial review or with a subsequent modification.

Documentation of IRB Approval

The consent and consent documentation procedures described in the IRB Protocol constitute the IRB approved research procedures. Any changes to the consent procedures or materials must be reviewed and approved by submitting a modification prior to implementing them.

Approved consent materials receive an approval watermark in *Zipline* regardless of whether consent will be documented.

- When consent is being documented, it is best practice, though not required, to use the watermarked version of the consent form.
- Any non-watermarked version must exactly match the content and format of the IRB-approved, watermarked version.

TIP SHEET Consent: Related Considerations

Consideration	Summary Information
ClinicalTrials.gov	There are additional consent requirements for studies that meet the definition of an applicable clinical trial. **WEBPAGE Regulatory requirements for clinical trials**
Deception	Some research may require deception by deliberately misleading subjects about some aspect(s) of the research. Most often, the subject is deceived about the true purpose of the study in order to avoid biasing the results. Deception imposes special responsibilities on the researcher because it conflicts with the fundamental ethical principle that subject make an informed, voluntary decision to participate in research. Researchers are responsible for: • Justifying the use of deception in the IRB Protocol. • Describing any "de-briefing" procedure that will be used to later inform subjects about the withheld or misleading information, or providing a rationale for why de-briefing is not necessary or appropriate.
Genomic Data Sharing	Some funders require submission of genomic data to NIH-designated repositories. When this requirement applies, specific consent language must be included in the consent process. **GUIDANCE Genomic Data Sharing** **WORKSHEET Consent Requirements and Expectations for Genomic Data Sharing**
HIPAA Authorization or Waiver	Research consent and HIPAA authorization, and/or waivers for both, are generally obtained, or granted, concurrently for studies that include access to PHI. **GUIDANCE HIPAA**
Mandatory Reporting	Some types of research increase the likelihood that subjects will disclose information that triggers mandatory reporting requirements (e.g., child or elder abuse). Consent materials must inform subjects about the possibility of mandatory reporting when there is a reasonable possibility that mandatory reporting circumstances or events will be encountered during the research. **GUIDANCE Mandatory State Reporting**
Privacy and Confidentiality	Consent materials must inform subjects about the extent to which their participation will remain confidential (or not). If subject identifiers are collected, researchers must retain them according to applicable records retention policies. Subjects should not be told that identifiers will be destroyed at the end of the study if records retention requirements prohibit the destruction before the end of the retention period. Researchers should use the **GUIDANCE Data Security Protections** to identify the correct level of protections. Exceptions to the protections associated with any particular level can be requested in the IRB Protocol with appropriate justification. **UW Records Management Services**

TIP SHEET Consent: Related Considerations (cont.)

Consideration	Summary Information
Recruitment	Recruitment processes and materials such as advertisements, announcements, social media postings, and cold contact letters are generally considered to be part of the consent process and must undergo review by the IRB. With the exception of **cold contact** materials, researchers are encouraged to submit descriptions of recruitment materials rather than the materials themselves. However, the IRB may request any recruitment materials if they are needed for the review. There is additional guidance and information about recruitment in the instructions embedded in the **IRB Protocol** application form.
Return of Individual Results	Researchers should make every effort to return research results that are clinically actionable, valid, and suggest life-threatening or severe health consequences if not treated or addressed quickly. Other clinically actionable results should be offered if this can be accomplished without compromising the research and in compliance with applicable regulations such as CLIA laboratory certification. Any plan to return results must be summarized during the consent process. **GUIDANCE Return of Individual Results**
Significant Financial Conflict of Interest (FCOI)	The lead researcher is responsible for ensuring that all members of the research team are aware of, and comply with, UW Policy GIM 10. Any requirements described in a Financial Conflict of Interest Management Plan must be incorporated into the research. It is **HSD policy** that subjects be informed about the presence of a FCOI during the consent process and that any other consent-related measures in the Management Plan must be incorporated into the IRB application (e.g., if research staff with a conflict are not allowed to obtain consent from subjects). **SOP Financial Conflict of Interest**
Subject Payment	**The primary ethical issue with subject payment is undue influence:** the concern that payment will inappropriately influence subjects' decisions about participating in research and about staying in the study once enrolled. The IRB Protocol requests that researchers describe: the purpose of the payment (reimbursement, compensation, incentive); the total amount of payment; the schedule/timing of the payment; and whether it will be pro-rated if only some of the procedures are completed. If subjects earn $600 or more in research payments from UW during the calendar year, the UW reports that to the IRS as "miscellaneous income" and subjects must be informed of this. Subjects' Social Security Numbers (SSN) may need to be collected in order to receive payment (see **UW Financial Management requirements**). Researchers and the IRB should consider whether the consent process/form should inform subjects about the collection of SSN. The key issue is whether this information is important to the specific subject population. **GUIDANCE Subject Payment** **TEMPLATE Consent Form, Standard**

Version Number	Posted Date	Implementation Date	Summary of Changes
1.1	03/03/2022	03/03/2022	Add tip sheet on Reconsent
1.0	10/08/2021	10/08/2021	Newly implemented document

Key words: Consent