TIP SHEET Consent: A Meaningful Consent Process

Facilitating Informed Decision-Making

(Details: Consent Overview)

Research consent must be designed from the perspective of the subject population to ensure infor be od [illegible]

- 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: Consent Overview)

Consent is a continuous, dynamic, and interactive process. The process usually begins with the [illegible] recruitment materials, includes the consent interaction, and continues in post-enrollment communications. Subjects consider throughout a study whethe7 (o)-11et Tf9.96 0 0 9.96 wt wto gontinuesticipate.

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: 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

TIP SHEET Consent: Population-Specific Considerations

Vulnerable Populations and Consent (Details: 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: Diminished/Fluctuating Consent Capacity)

review the Consent Tip Sheet on Assent and Legally Authorized Representative

Subjects with comprehension barriers or who cannot write or speak (Details: 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: 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.

Children worksheet Consent Tip Sheet - 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.

Pregnant Women worksheet Neonates worksheet

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TIP SHEET Consent: Assent & Legally Authorized Representative

Subjects with Diminished or Fluctuating Consent Capacity (Details: Diminished and Fluctuating Consent Capacity)

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

TIP SHEET Consent: Reconsent and Ongoing Subject Communication

Reconsent and Ongoing Subject Communication (Details: Reconsent and Ongoing Subject Communication)

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 (review 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

Consideration	Summary Information
ClinicalTrials.gov	There are additional consent requirements for studies that meet the definition of an applicable clinical trial.