THE UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER

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Checklist for obtaining Informed Consent and Assent, Assessing Comprehension, and Documenting Informed Consent for Clinical Research

Preparing for Consent Discussion	
Approved Consent	• Use the most current IRB-approved version of the consent form when consenting subjects. Download a copy from iMedRIS. • ***No changes*** may be made to the consent form once approved; that is, there may be no cross outs, strike throughs, or additional wording added. If changes are needed, submit a *Form 2: Change/Request and Amendments Form* in iMedRIS. These changes must be approved prior to implementation.
Timing	• Informed consent from the subject, the legally authorized representative (LAR), or the parent(s)/legal guardian(s) must be obtained ***prior to initiating any research procedures***, including screening, unless the IRB has granted a waiver. • Plan to ***allow plenty of time*** for questions and a thorough discussion. • Once the consent discussion is complete, the investigator is required to sign the consent form within 72- hours..
Privacy	• Conduct the process in a manner and location that ensures participant privacy.
Qualified Person	• The key study personnel obtaining consent must be qualified and appropriately trained to explain the research and assess participant comprehension. • The person must be listed in Sections 3.0 and (415) of the IRB application as key personnel, although this person does not need to be listed in consent form, unless an investigator. • The investigator or person obtaining consent must not persuade or influence the potential research subject.
Consent Form	• Give prospective subject, LAR, or parent(s)/legal guardian(s) a copy of the consent form. • Potential research subject, LAR, or parent(s)/legal guardian(s) must have an opportunity to read the consent document. • Prospective subject, LAR, parent(s)/legal guardian(s) may take the consent document home to discuss with family, friend or advocate. • Do not read the consent form verbatim but do verbally describe the information below during the consent discussion*****.

Topics to Cover During Consent/Assent Discussion	
Remember	The prospective subject, LAR, or parent(s)/legal guardian(s) must be provided with the information that a reasonable person would want to have in deciding about study participation and must have the opportunity to discuss that information
Purpose	• Explain that this study involves research. • ***Why are you the researcher*** doing this study? What do you hope to find out? • ***Why is the subject*** being asked to participate? Use lay terms when consenting the subject. • Avoid scientific terms and jargon unless appropriate for the subject.

Procedures	• ***What, when, where and how?*** • What is involved in doing the research? • When, where, and how often will study visits or hospital stays take place? • What will occur at the visits? • Describe all experimental procedures that will be completed during the clinical trial. • Describe randomization process, if relevant. • Use tables/charts for complicated procedures and schedules.
Alternatives	• ***What other procedures or treatments (if any)*** are available for care of the subject? • Emphasize voluntariness of the research and that the subject may withdraw at any time.
Risks	• ***What*** are commonly reported risks/discomforts? • What are any serious or unknown risks? • Explain that the research treatment/procedure may involve unexpected risks. • How will risks be minimized? • Discuss any other burdens or inconveniences (e.g., time commitment, travel, etc.).
Benefits	• ***What*** are the potential benefits to subjects? • ***What*** are the potential benefits to society? • Explain subjects have the right to refuse treatment and not lose any benefits to which they are entitled. • Explain subjects may choose to stop participation in the clinical trial at any time without losing benefits to which they are entitled. • Be objective – some studies may benefit future patients instead of current study subjects.
Questions	• ***Whom*** to contact for more information? With concerns? With complaints? Research-related injury?

Other Topics to Cover in Consent/Assent Discussion	
Confidentiality	• ***How*** will records that identify the subject be kept secure? • Will specimens and/or data be stored for future research? If applicable, use separate repository consent form. • Will private information be shared with an outside entity, such as the UTHSC IRB, institution, FDA, DHHS, sponsor, etc.? • Release of PHI should also be explained, if applicable.
Financial Issues	• ***What costs*** will the subject/insurance need to cover? • Will study or sponsor cover any costs? • Will the subject be **paid**? • When and how will **payments** be made? • Who will receive the payment if consent is obtained from the LAR or parent(s)/legal guardian(s)?
Withdrawal from Study	• ***How*** can the subject stop participating in the study? • Will special provisions need to be made to withdraw a subject's participation safely? • Will the research and procedures require a slow and organized end of participation?
Ongoing Consent and Assent	• ***How*** will the subject be informed of any changes in the study or significant new findings that may affect his or her willingness to continue participation? • When a child reaches **8 years of age** while enrolled in a research study, the assent should be obtained from the child subject.

	• When a child subject reaches the **age of majority** while enrolled in a research study, the subject should be consented as an adult. • When consent has been obtained from the **LAR** due to incompetence of the subject at the time of study entry in a study and the subject regains competence during study participation, the consent must be obtained to secure the subject's non-objection to continued participation in the study.

Tips for Ensuring Comprehension	
Guides and Checklists	Highlight important information from consent form to help guide discussion. Use a checklist to help guide or track discussion if that is helpful to you. Templates for the consent discussion and note-to-file located on the UTHSC IRB website can be found here.
Interactive Conversation	Ask potential subject to repeat or paraphrase understanding of different points of discussion. Ask open-ended questions or non-directive (i.e., questions that begin with who, what, when, how or please describe). Encourage questions. Specifically ask if subject agrees to participate.
Pediatric Assent	**Each child aged 8-17 years of age must provide assent**, provided that the investigator determines that the child is capable of assent by evaluating the child's level of maturity, psychosocial and emotional capacity, as well as the nature of the study. The assent process is a vital component of the investigator's ongoing relationship with the minor. Thus, adequate provision must be made for engaging those minors capable of participating in the process. Clinical judgment should be utilized to adapt the process and content to the minor's age, developmental and social maturity, family dynamics, culture, and experience in the medical setting.

Documenting Consent and Assent	
Required Signatures	• Once an individual agrees, or legally authorized representative [LAR] or parent (s)/legal guardian(s) agrees on subject's behalf, to participate in study, subject (or LAR or parent(s)/legal guardian(s) should sign, date, and time the consent form. • Subjects 8-13 years of age must sign, date, and time the Assent Discussion page of the consent form, if applicable to the study. • Subjects 14-17 years of age must sign, date and time the appropriate lines on consent form, if applicable to the study. • If adult assent is requested in the study application, the adult subject should sign, date, and time the Assent Discussion for Adult Subjects page in consent form. • The individual obtaining consent should sign, date, and time the consent form after the subject, LAR, or parent(s)/legal guardian(s). • The Investigator must sign, date, and time the consent form within 72-hours of the date the consent discussion occurred.
Copies to Subjects and Records	• Give subject, LAR, or parent(s)/legal guardian(s) a **copy of the consent form**. • Place a copy of the signed consent form in the medical record of subject, if required. **Please note** that our affiliate institutions have institutional policies that may require placing signed consent forms in the medical record.

Notes in Records	• **Document in the research record**, such as a checklist, that the potential subject met the inclusion criteria and did not meet the exclusion criteria before a subject is consented for participation in the study or for participation in screening for the study. The UTHSC IRB provides a template on the IRB website at https://uthsc.edu/research/compliance/irb/researchers/tools-guides.php • The proceedings of the informed **consent interview should be documented in the research record**. The IRB provides a template on the IRB website at https://uthsc.edu/research/compliance/irb/researchers/tools-guides.php • If applicable, **documentation of the assent process** should be included in the research record. • The **original signed consent form** must be placed in the research record or an electronic copy of the signed original as long as the controls delineated in 21 CFR 11.10 are in place for the closed system in which the electronic copy is stored

For additional information review the **Informed Consent and Confidentiality** policie as well as the **Vulnerable Populations in Research** policies located on the IRB Standard Operating Procedures page of the IRB website.

*****See "Informed Consent of Subjects Who Do Not Speak English, Illiterate English-Speaking Subjects, and Visually/Hearing Impaired Subjects" on IRB website when consenting non-English speaking, Illiterate, and/or Visually/Hearing Impaired subjects."