TEMPLATE

Consent to Act as a Subject in an Experimental Study

I. Purpose of the Study:
The objective of the study is to……(Describe the purpose of the study, background information, and an estimate of how many people will be in the study both locally and nationally).

II. Procedures to be Followed:
Briefly but completely describe the procedures involved.

III. Potential Risks of Participation in the Study:
Include nature of the risks (physical/psychological). Please also state if risks are minimal or if no risks are foreseen by participation in this study.

IV. Potential Benefits:
Include those benefits that may occur….possible wording:
The only anticipated direct benefit to you from your participation in this study is the satisfaction of knowing that you are helping to increase the knowledge of medical science on … . No other direct benefit from participation is expected.

V. Alternative Therapy:
The alternative to your participation in this study is your decision not to participate and/or alternative therapy described here.

VI. Confidentiality of Study:
See HIPAA Authorization Template (may be inserted here).
If de-identified, please state that all information is de-identified.
Describe methods to be use to keep information/records confidential

VII. Compensation/Liability:
There will be no payment to you for participation in this study. In the case of injury or illness resulting from this study, emergency medical treatment is available but will be provided at the usual charge. No funds have been set aside to compensate you in the event of injury. However, by signing this form, you are not giving up any legal rights to seek to obtain compensation for injury.

VIII. Research Related Inquiries:
Any questions concerning this study may be addressed to the Investigator: Provide local contact info here

IX. Patient Rights Information:
General questions concerning your rights as a participant in research protocols or questions about research related issues may be addressed to the Institutional Review Board Chairman, East Tennessee Children's Hospital, at (865) 541-8290.

If you have any questions or concerns that you feel you would like to discuss with someone who is not on the research team, you may also call the Office of Patient Experience at (865) 541-8586.

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X. Voluntary Participation Statement:

Participation in this study is voluntary. There will be no penalty or loss of benefits for refusal to participate, and you may withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled.

XI. Participant Contract:

I have received a copy of this consent form. I certify that I have read the above consent form and that I have received satisfactory explanations of the potential risks and benefits. I willingly volunteer and give my consent to participate in this study.

_____
Participant Name

_____ _____
Signature of Participant Date

_____ _____
Signature of Person Obtaining Consent Date