TEMPLATE

Parental Permission for My Child to Act as a Subject in a Research 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). Using "your child language."

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 from your child's 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 child's participation in this study is your child's decision not to participate and/or alternative therapy.

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

VII. Compensation/Liability:
There will be no payment to you or your child for their 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 your child 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:
Please include local contact info here:

IX. Patient Rights Information:
General questions concerning your child's 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 your child may withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled.

XI. Parental Permission/Patient Consent:

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

_____
Patient Name

_____ _____
Signature of Parent Date

_____ _____
Signature of Person Obtaining Permission Date

ASSENT TO THE CHILD AGE OF 7 – 13 YEARS:

I have explained this research to this patient in age appropriate terms and the patient has given verbal assent to participate in this research.

_____ _____
Signature of Person obtaining assent Date