Consent documents – Version 2.1 – January 17, 2020
Summary of changes

Contents

Adult Consent Form

Section	Previous	New	Rationale
Header	IRB Template Version 2.0-12/5/2018 **DO NOT CHANGE THIS FIELD-IRB USE ONLY**	IRB TEMPLATE Version 2.1 – 1/17/2020- Do not alter this text box	IRB template version section has been reformatted to take up less space.
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How will information about you be protected?	N/A	You will sign a separate HIPAA form	Make it clear that the consent form is not HIPAA Authorization.
What will happen if you are injured by this research?	All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. You do not give up any of your legal rights by signing this form.	All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries. If you think you have been injured from taking part in this study, call Dr. (PI Name) at (24 hour phone number). He/she will let you know what you should do. By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.	The approved injury language for Investigator-Initiated greater than minimal risk studies was updated to reflect currently approved template language. In addition, the sentence regarding contact was updated to reduce the number of places that require customization in an attempt to decrease customization errors
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Signature section	N/A	_____ Signature of Witness if applicable; e.g. literacy issues, visually impaired, physically unable to sign, witness/interpreter for non-English speaking participants using the short form) _____ Date _____ Printed Name of Witness	Adding a witness signature line to be used when applicable/approved

Information or Fact Sheet

Section	Previous	New	Rationale
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Parental Permission Form

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Assent Form Ages 15-17

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Consent addendum

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Short form

Section	Previous	New	Rationale
Header		IRB TEMPLATE Version 2.1 – 1/17/2020- Do not alter this text box	IRB template version section has been reformatted to take up less space.
Signature section	N/A	_____ Signature of Witness if applicable; e.g. literacy issues, visually impaired, physically unable to sign, witness/interpreter for non-English speaking participants using the short form) _____ Date _____ Printed Name of Witness	Adding a witness signature line to be used when applicable/approved

Assent Form Ages 7-14

Section	Previous	New	Rationale
Header	IRB Template Version 2.0-12/5/2018 **DO NOT CHANGE THIS FIELD-IRB USE ONLY**	IRB TEMPLATE Version 2.1 – 1/17/2020- Do not alter this text box	IRB template version section has been reformatted to take up less space.