Consent documents – August 5, 2024
Summary of changes

Adult Consent Form

Section	Previous	New	Rationale
What will happen if you are injured by this research?	OPTION A – no commercial sponsor: 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 the Principal Investigator at the phone number provided on this consent form. They 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. OPTION B: Injury language for industry **sponsored** studies. This section cannot be modified without the approval of the Office of Clinical Trials. If alternative language is approved by OCT please upload the SIL approval letter in PI	OPTION A – no commercial sponsor: If you think you have been injured because of taking part in this study, tell the study doctor or the contact on the front page of this document as soon as possible. You can provide this information in person or call them at the phone number listed in this consent form. The study doctor or someone on the study team can help you get the care you need. If you are injured because of this study, UNC will provide necessary medical treatment. You can also see another doctor for treatment, or if you have an urgent injury call 911. UNC at Chapel Hill [and/or the study Sponsor; *include if external Sponsor*] 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 and your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study-related injuries. By signing this form, you do not give up your right to seek payment or other risks if you are harmed as a result of being in this study. OPTION B: **Injury language for industry sponsored studies.** This section cannot be modified without the approval of the Clinical Research Compliance Office (CRCO). Doing so may result in IRB approval delay.	Update to Subject Injury Language from Office of University Counsel.

	attachments. Failure to do so may result in approval delay. Contact OCT at sil@unc.edu for questions regarding alterations to injury language.. 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. The Sponsor of the study has agreed to pay all reasonable medical expenses for the treatment of reactions, illnesses or injuries related to the use of the study drug/device, defects in the manufacture of the study drug/device, or as a direct result of properly performed study tests and/or procedures, except to the extent such expenses are due to the negligence of the study staff or due to your current disease or condition unless it is made worse because you are taking part in this study. The Sponsor has not set aside funds to pay for lost wages or any other losses or expenses. Any costs for medical expenses not paid by the Sponsor 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. To pay these medical expenses, the Sponsor will need to know some information about you like your name, date of birth, and social security number. This is because the Sponsor has to check to see if you have health care insurance through Medicare, and if so, report to Medicare the payment the Sponsor makes toward your medical expenses. We will not collect your social security number for this purpose unless you	Contact CRCO at SIL@unc.edu if you have questions. If you think you have been injured because of taking part in this study, tell the study doctor or the contact on the front page of this document as soon as possible. You can provide this information in person or call them at the phone number listed in this consent form. The study doctor or someone on the study team can help you get the care you need. If you are injured because of this study, UNC will provide necessary medical treatment. You can also see another doctor for treatment, or if you have an urgent injury call 911. The study sponsor [enter sponsor name] may pay for the cost of medical treatment for your injury. Your study doctor and the study sponsor will work together to determine what costs associated with your injury may be covered by the study sponsor. If the study sponsor pays any part of the cost of medical treatment for your injury, the study sponsor will need to know information about you like your name, date of birth, and Medicare Beneficiary or social security number. This information is needed because the study sponsor must check to see if you have health care insurance through Medicare. If you have Medicare, the study sponsor must report to Medicare the payment that has been made toward your medical expenses for the injury. The study team will not collect your Medicare Beneficiary or social security number unless you are injured and a claim is submitted to the study sponsor to pay medical expenses. If the study sponsor does not pay, you will be responsible for all costs. Your insurance company may reimburse you for some costs. You will be responsible for deductibles, co-payments, and co-insurance for treatments that are billed to	

	are injured and a claim is submitted to the Sponsor to pay medical expenses. If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They 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.	your insurance company. You should check with your insurance company about any such payments. Since this is a research study, some health insurance plans may not pay for any costs. There are no plans to pay you directly or give you any other type of compensation should you be injured because of taking part in this study. However, signing this consent form does not mean you give up or otherwise waive your rights to seek payment for injuries arising from the study.	

Assent form 15-17

Section	Previous	New	Rationale
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	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. OPTION B: Injury language for industry **sponsored** studies. This section cannot be modified without the approval of the Office of Clinical Trials. If alternative language is approved by OCT please upload the SIL approval letter in PI attachments. Failure to do so may result in approval delay. Contact OCT at sil@unc.edu for questions regarding alterations to injury language.. 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. The Sponsor of the study has agreed to pay all reasonable medical expenses for the treatment of reactions, illnesses or injuries related to the use of the study drug/device, defects in the manufacture of the study drug/device, or as a direct result of properly performed study tests and/or procedures, except to the extent such expenses are due to the negligence of the study staff or due to your current disease or condition unless it is made worse because you are taking part in this study. The Sponsor has not set aside funds to pay for lost wages or any other losses or expenses. Any costs for medical expenses not paid by the Sponsor 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.	not cover the costs of study-related injuries. By signing this form, you do not give up your right to seek payment or other risks if you are harmed as a result of being in this study. OPTION B: **Injury language for industry sponsored studies.** This section cannot be modified without the approval of the Clinical Research Compliance Office (CRCO). Doing so may result in IRB approval delay. Contact CRCO at SIL@unc.edu if you have questions. If you think you have been injured because of taking part in this study, tell the study doctor or the contact on the front page of this document as soon as possible. You can provide this information in person or call them at the phone number listed in this consent form. The study doctor or someone on the study team can help you get the care you need. If you are injured because of this study, UNC will provide necessary medical treatment. You can also see another doctor for treatment, or if you have an urgent injury call 911. The study sponsor [enter sponsor name] may pay for the cost of medical treatment for your injury. Your study doctor and the study sponsor will work together to determine what costs associated with your injury may be covered by the study sponsor. If the study sponsor pays any part of the cost of medical treatment for your injury, the study sponsor will need to know information about you like your name, date of birth, and Medicare Beneficiary or social security number. This information is needed because the study sponsor must check to see if you have health care insurance through Medicare. If you have Medicare, the study sponsor must report to Medicare the payment that has been made toward your medical expenses for the injury. The study team will	

	To pay these medical expenses, the Sponsor will need to know some information about you like your name, date of birth, and social security number. This is because the Sponsor has to check to see if you have health care insurance through Medicare, and if so, report to Medicare the payment the Sponsor makes toward your medical expenses. We will not collect your social security number for this purpose unless you are injured and a claim is submitted to the Sponsor to pay medical expenses. If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They 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.	not collect your Medicare Beneficiary or social security number unless you are injured and a claim is submitted to the study sponsor to pay medical expenses. If the study sponsor does not pay, you will be responsible for all costs. Your insurance company may reimburse you for some costs. You will be responsible for deductibles, co-payments, and co-insurance for treatments that are billed to your insurance company. You should check with your insurance company about any such payments. Since this is a research study, some health insurance plans may not pay for any costs. There are no plans to pay you directly or give you any other type of compensation should you be injured because of taking part in this study. However, signing this consent form does not mean you give up or otherwise waive your rights to seek payment for injuries arising from the study.	

Information or Fact Sheet

Section	Previous	New	Rationale
What will happen if you are injured by this research?	OPTION A – no commercial sponsor: 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	OPTION A – no commercial sponsor: If you think you have been injured because of taking part in this study, tell the study doctor or the contact on the front page of this document as soon as possible. You can provide this information in person or call them at the phone number listed in this consent form. The study doctor or someone on the study team can help you get the care you need. If you are	Update to Subject Injury Language from Office of University Counsel.

	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 the Principal Investigator at the phone number provided on this consent form. They 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. OPTION B: Injury language for industry **sponsored** studies. This section cannot be modified without the approval of the Office of Clinical Trials. If alternative language is approved by OCT please upload the SIL approval letter in PI attachments. Failure to do so may result in approval delay. Contact OCT at sil@unc.edu for questions regarding alterations to injury language.. 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. The Sponsor of the study has agreed to pay all reasonable medical expenses for the treatment of reactions, illnesses or injuries related to the use of the study drug/device, defects in the manufacture of the study drug/device, or as a direct result of properly performed study tests and/or procedures, except to the extent such expenses are due to the negligence of the study staff	injured because of this study, UNC will provide necessary medical treatment. You can also see another doctor for treatment, or if you have an urgent injury call 911. UNC at Chapel Hill [and/or the study Sponsor; *include if external Sponsor*] 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 and your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study-related injuries. By signing this form, you do not give up your right to seek payment or other risks if you are harmed as a result of being in this study. OPTION B: **Injury language for industry sponsored studies.** This section cannot be modified without the approval of the Clinical Research Compliance Office (CRCO). Doing so may result in IRB approval delay. Contact CRCO at SIL@unc.edu if you have questions. If you think you have been injured because of taking part in this study, tell the study doctor or the contact on the front page of this document as soon as possible. You can provide this information in person or call them at the phone number listed in this consent form. The study doctor or someone on the study team can help you get the care you need. If you are injured because of this study, UNC will provide necessary medical treatment. You can also see another doctor for treatment, or if you have an urgent injury call 911. The study sponsor [enter sponsor name] may pay for the cost of medical treatment for your injury. Your study doctor and the study sponsor will work together to determine what costs associated with your injury may be covered by the study sponsor.	

	or due to your current disease or condition unless it is made worse because you are taking part in this study. The Sponsor has not set aside funds to pay for lost wages or any other losses or expenses. Any costs for medical expenses not paid by the Sponsor 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. To pay these medical expenses, the Sponsor will need to know some information about you like your name, date of birth, and social security number. This is because the Sponsor has to check to see if you have health care insurance through Medicare, and if so, report to Medicare the payment the Sponsor makes toward your medical expenses. We will not collect your social security number for this purpose unless you are injured and a claim is submitted to the Sponsor to pay medical expenses. If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They 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.	If the study sponsor pays any part of the cost of medical treatment for your injury, the study sponsor will need to know information about you like your name, date of birth, and Medicare Beneficiary or social security number. This information is needed because the study sponsor must check to see if you have health care insurance through Medicare. If you have Medicare, the study sponsor must report to Medicare the payment that has been made toward your medical expenses for the injury. The study team will not collect your Medicare Beneficiary or social security number unless you are injured and a claim is submitted to the study sponsor to pay medical expenses. If the study sponsor does not pay, you will be responsible for all costs. Your insurance company may reimburse you for some costs. You will be responsible for deductibles, co-payments, and co-insurance for treatments that are billed to your insurance company. You should check with your insurance company about any such payments. Since this is a research study, some health insurance plans may not pay for any costs. There are no plans to pay you directly or give you any other type of compensation should you be injured because of taking part in this study. However, signing this consent form does not mean you give up or otherwise waive your rights to seek payment for injuries arising from the study.	

Parental Permission Form

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	provided on this consent form. They 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.	There are no plans to pay you directly or give you any other type of compensation should you be injured because of taking part in this study. However, signing this consent form does not mean you give up or otherwise waive your rights to seek payment for injuries arising from the study.	

Stored Specimens with Identifiers Consent Form

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What will happen if you are injured by this research?	OPTION A – no commercial sponsor: 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	OPTION A – no commercial sponsor: If you think you have been injured because of taking part in this study, tell the study doctor or the contact on the front page of this document as soon as possible. You can provide this information in person or call them at the phone number listed in this consent form. The study doctor or someone on the study team can help you get the care you need. If you are injured because of this study, UNC will provide necessary	Update to Subject Injury Language from Office of University Counsel.

	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 the Principal Investigator at the phone number provided on this consent form. They 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. OPTION B: Injury language for industry **sponsored** studies. This section cannot be modified without the approval of the Office of Clinical Trials. If alternative language is approved by OCT please upload the SIL approval letter in PI attachments. Failure to do so may result in approval delay. Contact OCT at sil@unc.edu for questions regarding alterations to injury language.. 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. The Sponsor of the study has agreed to pay all reasonable medical expenses for the treatment of reactions, illnesses or injuries related to the use of the study drug/device, defects in the manufacture of the study drug/device, or as a direct result of properly performed study tests and/or procedures, except to the extent such expenses are due to the negligence of the study staff	medical treatment. You can also see another doctor for treatment, or if you have an urgent injury call 911. UNC at Chapel Hill [and/or the study Sponsor; *include if external Sponsor*] 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 and your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study-related injuries. By signing this form, you do not give up your right to seek payment or other risks if you are harmed as a result of being in this study. OPTION B: **Injury language for industry sponsored studies.** This section cannot be modified without the approval of the Clinical Research Compliance Office (CRCO). Doing so may result in IRB approval delay. Contact CRCO at SIL@unc.edu if you have questions. If you think you have been injured because of taking part in this study, tell the study doctor or the contact on the front page of this document as soon as possible. You can provide this information in person or call them at the phone number listed in this consent form. The study doctor or someone on the study team can help you get the care you need. If you are injured because of this study, UNC will provide necessary medical treatment. You can also see another doctor for treatment, or if you have an urgent injury call 911. The study sponsor [enter sponsor name] may pay for the cost of medical treatment for your injury. Your study doctor and the study sponsor will work together to determine what costs associated with your injury may be covered by the study sponsor. If the study sponsor pays any part of the cost of medical treatment for your injury, the study sponsor will need to	

	or due to your current disease or condition unless it is made worse because you are taking part in this study. The Sponsor has not set aside funds to pay for lost wages or any other losses or expenses. Any costs for medical expenses not paid by the Sponsor 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. To pay these medical expenses, the Sponsor will need to know some information about you like your name, date of birth, and social security number. This is because the Sponsor has to check to see if you have health care insurance through Medicare, and if so, report to Medicare the payment the Sponsor makes toward your medical expenses. We will not collect your social security number for this purpose unless you are injured and a claim is submitted to the Sponsor to pay medical expenses. If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They 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.	know information about you like your name, date of birth, and Medicare Beneficiary or social security number. This information is needed because the study sponsor must check to see if you have health care insurance through Medicare. If you have Medicare, the study sponsor must report to Medicare the payment that has been made toward your medical expenses for the injury. The study team will not collect your Medicare Beneficiary or social security number unless you are injured and a claim is submitted to the study sponsor to pay medical expenses. If the study sponsor does not pay, you will be responsible for all costs. Your insurance company may reimburse you for some costs. You will be responsible for deductibles, co-payments, and co-insurance for treatments that are billed to your insurance company. You should check with your insurance company about any such payments. Since this is a research study, some health insurance plans may not pay for any costs. There are no plans to pay you directly or give you any other type of compensation should you be injured because of taking part in this study. However, signing this consent form does not mean you give up or otherwise waive your rights to seek payment for injuries arising from the study.	