# Consent documents – August 5, 2024 Summary of changes

### **Adult Consent Form**

Section	Previous	New	Rationale
What will happen	OPTION A – no commercial sponsor:		Update to Subject Injury
if you are injured	All research involves a chance that something bad might	OPTION A – no commercial sponsor:	Language from Office of
by this research?	happen to you. If you are hurt, become sick, or develop a	If you think you have been injured because of taking part in	University Counsel.
	reaction from something that was done as part of this study, the	this study, tell the study doctor or the contact on the front	
	researcher will help you get medical care, but the University of	page of this document as soon as possible. You can provide	
	North Carolina at Chapel Hill has not set aside funds to pay you	this information in person or call them at the phone number	
	for any such injuries, illnesses or reactions, or for the related	listed in this consent form. The study doctor or someone on	
	medical care. Any costs for medical expenses will be billed to	the study team can help you get the care you need. If you are	
	you or your insurance company. You may be responsible for	injured because of this study, UNC will provide necessary	
	any co-payments and your insurance may not cover the costs of	medical treatment. You can also see another doctor for	
	study related injuries.	treatment, or if you have an urgent injury call 911.	
	TC 41:1 1 1 1: 1C 41: 4:4:	UNC at Chapel Hill [and/or the study Sponsor; include if	
	If you think you have been injured from taking part in this	external Sponsor] has not set aside funds to pay you for any	
	study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what	such injuries, illnesses, or reactions, or for the related	
	you should do.	medical care. Any costs for medical expenses will be billed to you and your insurance company. You may be	
	you should do.	responsible for any co-payments and your insurance may	
	By signing this form, you do not give up your right to seek	not cover the costs of study-related injuries.	
	payment or other rights if you are harmed as a result of being in	By signing this form, you do not give up your right to seek	
	this study.	payment or other risks if you are harmed as a result of being	
	tins study.	in this study.	
	OPTION B: Injury language for industry <b>sponsored</b> studies.	•	
	This section cannot be modified without the approval of the	OPTION B: Injury language for industry sponsored	
	Office of Clinical Trials. If alternative language is approved by	studies. This section cannot be modified without the	
	OCT please upload the SIL approval letter in PI	approval of the Clinical Research Compliance Office	
	De l'preuse aproud tile ord approvarienter in l'i	(CRCO). Doing so may result in IRB approval delay.	

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, copayments, and co-insurance for treatments that are billed to

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

#### Assent form 15-17

Section	Previous	New	Rationale
What will happen	OPTION A – no commercial sponsor:		Update to Subject Injury
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.	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	Update to Subject Injury Language from Office of University Counsel.

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

#### Information or Fact Sheet

Section	Previous	New	Rationale
What will happen	OPTION A – no commercial sponsor:		Update to Subject Injury
if you are injured	All research involves a chance that something bad might	OPTION A – no commercial sponsor:	Language from Office of
by this research?	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	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	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, copayments, 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

Section	Previous	New	Rationale
What will happen	OPTION A – no commercial sponsor:		Update to Subject Injury
if you are injured	All research involves a chance that something bad might	OPTION A – no commercial sponsor:	Language from Office of
by this research?	happen to you. If you are hurt, become sick, or develop a	If you think you have been injured because of taking part in	University Counsel.
	reaction from something that was done as part of this study, the	this study, tell the study doctor or the contact on the front	
	researcher will help you get medical care, but the University of	page of this document as soon as possible. You can provide	
	North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related	this information in person or call them at the phone number	
	medical care. Any costs for medical expenses will be billed to	listed in this consent form. The study doctor or someone on	
	you or your insurance company. You may be responsible for	the study team can help you get the care you need. If you are injured because of this study, UNC will provide necessary	
	any co-payments and your insurance may not cover the costs of	medical treatment. You can also see another doctor for	
	study related injuries.	treatment, or if you have an urgent injury call 911.	
		UNC at Chapel Hill [and/or the study Sponsor; include if	
	If you think you have been injured from taking part in this	external Sponsor] has not set aside funds to pay you for any	
	study, call the Principal Investigator at the phone number	such injuries, illnesses, or reactions, or for the related	
	provided on this consent form. They will let you know what	medical care. Any costs for medical expenses will be billed	
	you should do.	to you and your insurance company. You may be	
		responsible for any co-payments and your insurance may	
	By signing this form, you do not give up your right to seek	not cover the costs of study-related injuries.	
	payment or other rights if you are harmed as a result of being in	By signing this form, you do not give up your right to seek	
	this study.	payment or other risks if you are harmed as a result of being in this study.	
	OPTION B: Injury language for industry <b>sponsored</b> studies.		
	This section cannot be modified without the approval of the	OPTION B: Injury language for industry sponsored	
	Office of Clinical Trials. If alternative language is approved by	studies. This section cannot be modified without the	
	OCT please upload the SIL approval letter in PI	approval of the Clinical Research Compliance Office (CRCO). Doing so may result in IRB approval delay.	
	attachments. Failure to do so may result in approval delay.	Contact CRCO at SIL@unc.edu if you have questions.	
	Contact OCT at sil@unc.edu for questions regarding alterations	If you think you have been injured because of taking part in	
	to injury language	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	

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 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

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, copayments, 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.

provided on this consent form. They will let you know what you should do.	There are no plans to pay you directly or give you any other type of compensation should you be injured because of
By signing this form, you do not give up your right to seek	taking part in this study. However, signing this consent form does not mean you give up or otherwise waive your

# Stored Specimens with Identifiers Consent Form

Section	Previous	New	Rationale
What will happen	OPTION A – no commercial sponsor:		Update to Subject Injury
if you are injured	All research involves a chance that something bad might	OPTION A – no commercial sponsor:	Language from Office of
by this research?	happen to you. If you are hurt, become sick, or develop a	If you think you have been injured because of taking part in	University Counsel.
	reaction from something that was done as part of this study, the	this study, tell the study doctor or the contact on the front	
	researcher will help you get medical care, but the University of	page of this document as soon as possible. You can provide	
	North Carolina at Chapel Hill has not set aside funds to pay you	this information in person or call them at the phone number	
	for any such injuries, illnesses or reactions, or for the related	listed in this consent form. The study doctor or someone on	
	medical care. Any costs for medical expenses will be billed to	the study team can help you get the care you need. If you are	
	you or your insurance company. You may be responsible for	injured because of this study, UNC will provide necessary	
	any co-payments and your insurance may not cover the costs of	medical treatment. You can also see another doctor for	
	study related injuries.	treatment, or if you have an urgent injury call 911.	
		UNC at Chapel Hill [and/or the study Sponsor; include if	
	If you think you have been injured from taking part in this	external Sponsor has not set aside funds to pay you for any	
	study, call the Principal Investigator at the phone number	such injuries, illnesses, or reactions, or for the related	
	provided on this consent form. They will let you know what	medical care. Any costs for medical expenses will be billed	
	you should do.	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	

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. 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 not collect your Medicare Beneficiary or social security

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

### Stored Specimens without Identifiers Consent Form

Section	Previous	New	Rationale
What will happen	OPTION A – no commercial sponsor:		Update to Subject Injury
if you are injured	All research involves a chance that something bad might	OPTION A – no commercial sponsor:	Language from Office of
by this research?	happen to you. If you are hurt, become sick, or develop a	If you think you have been injured because of taking part in	University Counsel.
	reaction from something that was done as part of this study, the	this study, tell the study doctor or the contact on the front	
	researcher will help you get medical care, but the University of	page of this document as soon as possible. You can provide	
	North Carolina at Chapel Hill has not set aside funds to pay you	this information in person or call them at the phone number	
	for any such injuries, illnesses or reactions, or for the related	listed in this consent form. The study doctor or someone on	
	medical care. Any costs for medical expenses will be billed to	the study team can help you get the care you need. If you are	
	you or your insurance company. You may be responsible for	injured because of this study, UNC will provide necessary	

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, copayments, 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.