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

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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.
What if we learn	The [MRI, CT, X-ray, etc.] we are using in this research study is not	The imaging we are using in this research study is not the same	Results template language
about new findings	the same quality as a [MRI, CT, X-ray, etc.] that you may have as part	quality as imaging that you may have as part of your health care.	(scenario 1) has been revised to
or information	of your health care. The images from the [MRI, CT, X-ray, etc.] will	The images will not be reviewed by a doctor who normally reads	reduce the number of places that
during the study?	not be reviewed by a doctor who normally reads such images (such	such images (such as a radiologist). As a result, you may not be	require customization in an attempt
	as a radiologist). As a result, you may not be informed of any	informed of any unexpected findings. The results will not be	to decrease customization errors.

unexpected findings. The results of your [MRI, CT, X-ray, etc.] will not be placed in your medical record. Occasionally the technologist or principal investigator may notice something abnormal on the imaging. If this does occur, the images will be reviewed by a qualified radiologist to determine if there is anything of clinical importance. If something is found to be important then you, and/or your primary care provider will be notified. Any further follow up and costs associated with the incidental finding will be your responsibility. There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as problems with getting insurance or a job, or feeling worried about a finding for which no treatment is required or appropriate).

Do you wish to be informed in case of clinical/relevant unexpected findings? Please initial in the box below if you do not wish to be notified of clinical/relevant unexpected findings. If you do not initial in the box, you will be notified of any findings.

I do not wish to be notified.

What if we learn about new findings or information during the study?

Whenever imaging [MRI, CT, X-ray, etc.] is done, there is the chance of finding something unexpected. Unexpected findings can have clinical significance, or no clinical significance. Clinically significant means that the [MRI, CT, X-ray, etc.] shows a problem that may or require further follow up or treatment. The imaging studies in this study will be reviewed by a qualified radiologist. You will be informed of any findings of clinical significance that may be discovered during the imaging procedure.

There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as problems with getting insurance or a job, or feeling worried about a finding for which no treatment is required or appropriate). The [MRI, CT, X-ray, etc.] we are using in this research study is not the same quality as a [MRI, CT, X-ray, etc.] that you may have as part of your health care. If you believe you are having symptoms that may require clinical imaging, you should contact your primary care physician.

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Returning of Imaging Results template language (scenario 2) has been revised to reduce the number of places that require customization in an attempt to decrease customization errors.

How will information about you be protected?	If a central site will be used to read research images your [MRI, CT, X-ray, etc.] will be conducted here at UNC no UNC physician will review the [MRI, CT, X-ray, etc.]. Rather, your images will be reviewed by a "central reader," a physician designated by the sponsor of this trial to review all of the images. We will inform you of any findings of clinical significance that the central reader tells us about. N/A	If a central site will be used to read research images, the imaging procedure will be conducted here at UNC no UNC physician will review the images. Rather, your images will be reviewed by a "central reader," a physician designated by the sponsor of this trial to review all of the images. We will inform you of any findings of clinical significance that the central reader tells us about. 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 copayments 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
What if you want to stop before your part in the study is complete?	N/A	Please select one or the other: 1) If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected or 2) If you withdraw or withdrawn from this study all data collected will be destroyed and no additional data will be collected (for non FDA regulated research only).	Added language to clarify to subjects what will happen to their data if they withdraw.

Signature section	N/A		Adding a witness signature line to
		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)	be used when applicable/approved
		Date	
		Printed Name of Witness	

Information or Fact Sheet

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If a central site will be used to read research images your [MRI, CT, X-ray, etc.] will be conducted here at UNC no UNC physician will review the [MRI, CT, X-ray, etc.]. Rather, your images will be reviewed by a "central reader," a physician designated by the sponsor of this trial to review all of the images. We will inform you of any findings of clinical significance that the central reader tells us about.

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If a central site will be used to read research **images**, **the imaging procedure** will be conducted here at UNC no UNC physician will review the **images**. Rather, your images will be reviewed by a "central reader," a physician designated by the sponsor of this trial to review all of the images. We will inform you of any findings of clinical significance that the central reader tells us about.

Returning of Imaging Results template language (scenario 2) has been revised to reduce the number of places that require customization in an attempt to decrease customization errors.

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 copayments 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). [the doctor listed on the first page of this form.] 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
What if you want to stop before your part in the study is complete?	N/A	Please select one or the other: 1) If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected or 2) If you withdraw or withdrawn from this study all data collected will be destroyed and no additional data will be collected (for non FDA regulated research only).	Added language to clarify to subjects what will happen to their data if they withdraw.
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	Adding a witness signature line to be used when applicable/approved

	Drinted Name of Wike as	
	Printed Name of Witness	

Parental Permission Form

Section	Previous	New	Rationale
Header	IRB Template	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
	Version 2.0-12/5/2018	IRB TEMPLATE VERSION 2.1 – 1/17/2020- DO NOT after this text box	space.
	DO NOT CHANGE THIS FIELD-IRB USE ONLY		space.
What if we learn	The [MRI, CT, X-ray, etc.] we are using in this research study is not	The imaging we are using in this research study is not the same	Results template language
about new findings	the same quality as a [MRI, CT, X-ray, etc.] that you may have as part	quality as imaging that you may have as part of your health care.	(scenario 1) has been revised to
or information	of your health care. The images from the [MRI, CT, X-ray, etc.] will	The images will not be reviewed by a doctor who normally reads	reduce the number of places that
during the study?	not be reviewed by a doctor who normally reads such images (such	such images (such as a radiologist). As a result, you may not be	require customization in an attempt
	as a radiologist). As a result, you may not be informed of any	informed of any unexpected findings. The results will not be	to decrease customization errors.
	unexpected findings. The results of your [MRI, CT, X-ray, etc.] will	placed in your medical record. Occasionally the technologist or	
	not be placed in your medical record. Occasionally the technologist	principal investigator may notice something abnormal on the	
	or principal investigator may notice something abnormal on the	imaging. If this does occur, the images will be reviewed by a	
	imaging. If this does occur, the images will be reviewed by a qualified radiologist to determine if there is anything of clinical	qualified radiologist to determine if there is anything of clinical importance. If something is found to be important then you,	
	importance. If something is found to be important then you, and/or	and/or your primary care provider will be notified. Any further	
	your primary care provider will be notified. Any further follow up	follow up and costs associated with the incidental finding will be	
	and costs associated with the incidental finding will be your	your responsibility. There may be benefits to learning such results	
	responsibility. There may be benefits to learning such results (such as	(such as early detection and treatment of a medical condition),	
	early detection and treatment of a medical condition), but there are	but there are risks as well (such as problems with getting	
	risks as well (such as problems with getting insurance or a job, or	insurance or a job, or feeling worried about a finding for which no	
	feeling worried about a finding for which no treatment is required or appropriate).	treatment is required or appropriate).	
		Do you wish to be informed in case of clinical/relevant	
	Do you wish to be informed in case of clinical/relevant unexpected	unexpected findings? Please initial in the box below if you do not	
	findings? Please initial in the box below if you do not wish to be	wish to be notified of clinical/relevant unexpected findings. If	
	notified of clinical/relevant unexpected findings. If you do not initial in the box, you will be notified of any findings.	you do not initial in the box, you will be notified of any findings.	
		I do not wish to be notified.	

	I do not wish to be notified.		
What if we learn	Whenever imaging [MRI, CT, X-ray, etc.] is done, there is the chance	Whenever imaging (e.g. MRI, CT, X-ray, etc.) is done, there is the	Returning of Imaging Results
about new findings	of finding something unexpected. Unexpected findings can have	chance of finding something unexpected. Unexpected findings	template language (scenario 2) has
or information	clinical significance, or no clinical significance. Clinically significant	can have clinical significance, or no clinical significance. Clinically	been revied to reduce the number
during the study?	means that the [MRI, CT, X-ray, etc.] shows a problem that may or	significant means that the imaging shows a problem that may or	of places that require customization
	require further follow up or treatment. The imaging studies in this	require further follow up or treatment. The imaging in this study	in an attempt to decrease
	study will be reviewed by a qualified radiologist. You will be informed	will be reviewed by a qualified radiologist. You will be informed of	customization errors.
	of any findings of clinical significance that may be discovered during	any findings of clinical significance that may be discovered during	
	the imaging procedure.	the imaging procedure.	
	There may be benefits to learning such results (such as early	There may be benefits to learning such results (such as early	
	detection and treatment of a medical condition), but there are risks	detection and treatment of a medical condition), but there are	
	as well (such as problems with getting insurance or a job, or feeling	risks as well (such as problems with getting insurance or a job, or	
	worried about a finding for which no treatment is required or	feeling worried about a finding for which no treatment is required	
	appropriate). The [MRI, CT, X-ray, etc.] we are using in this research	or appropriate). The imaging we are using in this research study is	
	study is not the same quality as a [MRI, CT, X-ray, etc.] that you may	not the same quality as imaging that you may have as part of	
	have as part of your health care. If you believe you are having	your health care. If you believe you are having symptoms that	
	symptoms that may require clinical imaging, you should contact your	may require clinical imaging, you should contact your primary	
	primary care physician.	care physician.	
	If a central site will be used to read research imagines your [MRI, CT,	If a central site will be used to read research images, the imaging	
	X-ray, etc.] will be conducted here at UNC no UNC physician will	procedure will be conducted here at UNC no UNC physician will	
	review the [MRI, CT, X-ray, etc.]. Rather, your images will be	review the images . Rather, your images will be reviewed by a	
	reviewed by a "central reader," a physician designated by the	"central reader," a physician designated by the sponsor of this	
	sponsor of this trial to review all of the images. We will inform you of	trial to review all of the images. We will inform you of any	
	any findings of clinical significance that the central reader tells us	findings of clinical significance that the central reader tells us	
	about.	about.	
What are the		The research team will make every effort to protect your	This line is added to clarify that
possible risks or		information, but there is a small risk of unwanted or accidental	there is always a risk of breach of
discomforts involved		disclosure.	confidentiality in any study that is
from being in this study?			storing data.
How will	N/A	V 211 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Make it clear that the consent form
information about	N/A	You will sign a separate HIPAA form	is not HIPAA Authorization.
you be protected?			is not mean authorization.
What will happen if	All research involves a chance that something bad might happen to	All research involves a chance that something bad might happen	The approved injury language for
you are injured by	you. This may include the risk of personal injury. In spite of all safety	to you. If you are hurt, become sick, or develop a reaction from	Investigator-Initiated greater than
this research?	measures, you might develop a reaction or injury from being in this	something that was done as part of this study, the researcher will	minimal risk studies was updated to
tino rescurent	study. If such problems occur, the researchers will help you get	help you get medical care, but the University of North Carolina at	reflect currently approved template
	medical care, but any costs for the medical care will be billed to you	Chapel Hill has not set aside funds to pay you for any such	language.
	1 sales sale, sat any soots for the medical care will be sinca to you		04490.

	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.	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 copayments 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.	
What if you want to stop before your part in the study is complete?	N/A	Please select one or the other: 1) If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected or 2) If you withdraw or withdrawn from this study all data collected will be destroyed and no additional data will be collected (for non FDA regulated research only).	Added language to clarify to subjects what will happen to their data if they withdraw.
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 15-17

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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	findings? Please initial in the box below if you do not wish to be notified of clinical/relevant unexpected findings. If you do not initial in the box, you will be notified of any findings. I do not wish to be notified.	wish to be notified of clinical/relevant unexpected findings. If you do not initial in the box, you will be notified of any findings. I do not wish to be notified.	
What if we learn about new findings or information during the study?	Whenever imaging [MRI, CT, X-ray, etc.] is done, there is the chance of finding something unexpected. Unexpected findings can have clinical significance, or no clinical significance. Clinically significant means that the [MRI, CT, X-ray, etc.] shows a problem that may or require further follow up or treatment. The imaging studies in this study will be reviewed by a qualified radiologist. You will be informed	Whenever imaging (e.g. MRI, CT, X-ray, etc.) is done, there is the chance of finding something unexpected. Unexpected findings can have clinical significance, or no clinical significance. Clinically significant means that the imaging shows a problem that may or require further follow up or treatment. The imaging in this study will be reviewed by a qualified radiologist. You will be informed of	Returning of Imaging Results template language (scenario 2) has been revised to reduce the number of places that require customization in an attempt to decrease customization errors.

What are the possible risks or discomforts involved from being in this	of any findings of clinical significance that may be discovered during the imaging procedure. There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as problems with getting insurance or a job, or feeling worried about a finding for which no treatment is required or appropriate). The [MRI, CT, X-ray, etc.] we are using in this research study is not the same quality as a [MRI, CT, X-ray, etc.] that you may have as part of your health care. If you believe you are having symptoms that may require clinical imaging, you should contact your primary care physician. If a central site will be used to read research imagines your [MRI, CT, X-ray, etc.] will be conducted here at UNC no UNC physician will review the [MRI, CT, X-ray, etc.]. Rather, your images will be reviewed by a "central reader," a physician designated by the sponsor of this trial to review all of the images. We will inform you of any findings of clinical significance that the central reader tells us about.	any findings of clinical significance that may be discovered during the imaging procedure. There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as problems with getting insurance or a job, or feeling worried about a finding for which no treatment is required or appropriate). The imaging we are using in this research study is not the same quality as a imaging that you may have as part of your health care. If you believe you are having symptoms that may require clinical imaging, you should contact your primary care physician. If a central site will be used to read research images, the imaging procedure will be conducted here at UNC no UNC physician will review the images . Rather, your images will be reviewed by a "central reader," a physician designated by the sponsor of this trial to review all of the images. We will inform you of any findings of clinical significance that the central reader tells us about. The research team will make every effort to protect your information, but there is a small risk of unwanted or accidental disclosure.	This line is added to clarify that there is always a risk of breach of confidentiality in any study that is storing data.
study? 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 copayments 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). [the doctor listed	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

		on the first page of this form.] 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.	
What if you want to	N/A	Please select one or the other: 1) If you withdraw or are	Added language to clarify to
stop before your		withdrawn from this study all data collected up until the point of	subjects what will happen to their
part in the study is		withdrawal will be retained, however no additional information	data if they withdraw.
complete?		will be collected or 2) If you withdraw or withdrawn from this	
		study all data collected will be destroyed and no additional data	
		will be collected (for non FDA regulated research only).	
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	Adding a witness signature line to be used when applicable/approved
		Printed Name of Witness	

Consent addendum

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.

Signature section	N/A		Adding a witness signature line to
		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)	be used when applicable/approved
		DatePrinted Name of Witness	

Short 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.
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.