
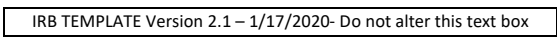


Consent documents – Version 2.1 – January 17, 2020 Summary of changes

Contents

Adult Consent Form	1
Information or Fact Sheet	4
Parental Permission Form.....	7
Assent Form Ages 15-17	9
Consent addendum	12
Short form.....	13
Assent Form Ages 7-14.....	14

Adult Consent Form


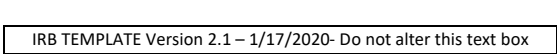
Section	Previous	New	Rationale
Header			IRB template version section has been reformatted to take up less space.
<u>What if we learn about new findings or information during the study?</u>	The [MRI, CT, X-ray, etc.] we are using in this research study is not the same quality as a [MRI, CT, X-ray, etc.]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

	<p>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).</p> <p>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.</p> <p>_____ I do not wish to be notified.</p>	<p>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).</p> <p>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.</p> <p>_____ I do not wish to be notified.</p>	
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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.	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.	
<u>How will information about you be protected?</u>	N/A	You will sign a separate HIPAA form	Make it clear that the consent form is not HIPAA Authorization.
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<u>What if you want to stop before your part in the study is complete?</u>	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	<p>_____</p> <p>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)</p> <p>_____</p> <p>Date</p> <p>_____</p> <p>Printed Name of Witness</p>	Adding a witness signature line to be used when applicable/approved
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Section	Previous	New	Rationale
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<u>How will information about you be protected?</u>	N/A	You will sign a separate HIPAA form	Make it clear that the consent form is not HIPAA Authorization.
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Signature section	N/A	<p>_____</p> <p>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)</p> <p>_____</p> <p>Date</p>	Adding a witness signature line to be used when applicable/approved

		_____ Printed Name of Witness	
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Parental Permission Form

Section	Previous	New	Rationale
Header	IRB Template Version 2.0-12/5/2018 **DO NOT CHANGE THIS FIELD-IRB USE ONLY**	IRB TEMPLATE Version 2.1 – 1/17/2020- Do not alter this text box	IRB template version section has been reformatted to take up less space.
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Header	<div style="background-color: #4a7ebb; color: white; padding: 5px; text-align: center;"> IRB Template Version 2.0-12/5/2018 **DO NOT CHANGE THIS FIELD-IRB USE ONLY** </div>	<div style="border: 1px solid black; padding: 2px; text-align: center; font-size: small;"> IRB TEMPLATE Version 2.1 – 1/17/2020- Do not alter this text box </div>	IRB template version section has been reformatted to take up less space.
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<u>What are the possible risks or discomforts involved from being in this study?</u>		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.
<u>How will information about you be protected?</u>	N/A	You will sign a separate HIPAA form	Make it clear that the consent form is not HIPAA Authorization.
<u>What will happen if you are injured by this research?</u>	All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. You do not give up any of your legal rights by signing this form.	All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries. If you think you have been injured from taking part in this study, call Dr. (PI Name) at (24 hour phone number). [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


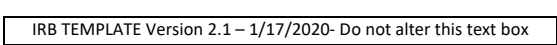
		<p>on the first page of this form.] He/she will let you know what you should do.</p> <p>By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.</p>	
<u>What if you want to stop before your part in the study is complete?</u>	N/A	<p>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).</p>	Added language to clarify to subjects what will happen to their data if they withdraw.
Signature section	N/A	<p>_____</p> <p>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)</p> <p>_____</p> <p>Date</p> <p>_____</p> <p>Printed Name of Witness</p>	Adding a witness signature line to be used when applicable/approved

Consent addendum

Section	Previous	New	Rationale
Header	<div style="background-color: #4a7ebb; color: white; padding: 10px; text-align: center;"> IRB Template Version 2.0-12/5/2018 **DO NOT CHANGE THIS FIELD-IRB USE ONLY** </div>	<div style="border: 1px solid black; padding: 5px; text-align: center;"> IRB TEMPLATE Version 2.1 – 1/17/2020- Do not alter this text box </div>	IRB template version section has been reformatted to take up less space.

Signature section	N/A	<p>_____</p> <p>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)</p> <p>_____</p> <p>Date</p> <p>_____ Printed</p> <p>Name of Witness</p>	Adding a witness signature line to be used when applicable/approved
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Short form

Section	Previous	New	Rationale
Header			IRB template version section has been reformatted to take up less space.
Signature section	N/A	<p>_____</p> <p>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)</p> <p>_____</p> <p>Date</p> <p>_____</p> <p>Printed Name of Witness</p>	Adding a witness signature line to be used when applicable/approved

Assent Form Ages 7-14

Section	Previous	New	Rationale
Header	<div data-bbox="470 334 962 483" style="background-color: #4a7ebb; color: white; padding: 10px; text-align: center;"> IRB Template Version 2.0-12/5/2018 **DO NOT CHANGE THIS FIELD-IRB USE ONLY** </div>	<div data-bbox="1249 358 1803 386" style="border: 1px solid black; padding: 2px;"> IRB TEMPLATE Version 2.1 – 1/17/2020- Do not alter this text box </div>	IRB template version section has been reformatted to take up less space.