Human Research Ethics Training Tips

UNC consent template updates & revisions (version updated 10/23/19)

1. Number of subjects statement in consent. Currently includes three places to customize, suggest writing more generally to reduce administrative burden. (Adult, Parental Permission)

   Current: A total of approximately number people at number institutions will take part in this study, including approximately number people from this institution.

   Revised: Approximately total number people at this institution (OR) multiple institutions will take part in this study.

2. Radiation, new findings. Currently includes six places to customize, suggest writing more generally to reduce administrative burden. (Adult, Parental Permission)

Current: 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.

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.

Revised:

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

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

Whenever imaging (e.g. MRI, CT, X-ray, ultrasound, 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 require further follow up or treatment. The imaging 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 imaging we are using in this research study is not the same quality as the 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 your imaging procedure will be conducted here at UNC but 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.

Revised tracked:

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

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 ~~[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 imaging ~~[MRI, CT, X-ray, etc.]~~ we are using in this research study is not the same quality as the imaging ~~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 imag~~in~~es your imaging procedure ~~[MRI, CT, X-ray, etc.]~~ will be conducted here at UNC but no UNC physician will review the images~~[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.

3.
Injury language. Need tag updated to reflect current injury language. (Adult, Parental Permission)

Current: **What will happen if you are injured by this research?**
This section may be omitted if the study involves no more than minimal risk and no chance of personal injury. The language below should be used if there is no commercial Sponsor; there is an alternative version for sponsored studies. To the extent they are known, describe any medical treatments for injury

that might be available or where the subject can obtain further information.

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.

Revised:

Currently approved Template Language as of May 2018:

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you think you have been injured from taking part in this study, call Dr. (PI Name) at (24 hour phone number). He/she will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study

Suggested revision to injury language October 2019:

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

4. Add statement (new tag) about signing a separate HIPAA Authorization if B.2.2 = yes. Include instructions to replace statement with external institution's HIPAA Authorization language if the external site combines their consent and HIPAA into a single document. Add tag at end of section on privacy and confidentiality. (Adult, Parental Permission)

Add: You will be asked to sign a separate form ("HIPAA Authorization") to allow researchers to review your medical records. (replace this statement with external institution's HIPAA authorization language if creating a site-specific consent form and the external site combines their consent and HIPAA into one single document)

5. Add witness line on signature page of consents. (Adult, Parental Permission)
   Add: _____
   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

6. Concise Summary text box, un-highlight 'CONCISE SUMMARY' as they should not be deleting these words. Add to instructions that they should keep the text box around the summary. (Adult, Parental Permission)

7. Withdrawal paragraph, add statement. Add at the end of section with header **What if you want to stop before**… (Adult, Parental Permission)

Add: 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 unless you provide additional written permission for further data collection at the time of your withdrawal or 2) If you withdraw or are withdrawn from this study all data collected will be destroyed and no additional data will be collected. (for non FDA regulated research only).