Consent documents – Version 2.0 – December 5, 2018
Summaries of changes

Contents

Adult Consent Form

Section	Previous	New	Rationale
Top of Header	N/A	IRB Template Version 2.0-12/5/2018 **DO NOT CHANGE THIS FIELD-IRB USE ONLY**	IRB template version has been added to facilitate review and tracking of consent document

			changes as IRB templates are updated.
Beginning of document, following the header	N/A	CONCISE SUMMARY The revised Common Rule requires that consent forms contain a concise presentation of key information. The intention of this section is to provide potential research participants with a better understanding of the project's scope, including major risks and benefits, so they can make a more fully informed decision about whether to participate. This section should include a summary of the purpose of the study, duration of participation, major requirements of the study and any potential benefits. This section should also contain any significant risks of participating in the study. The information presented in this section may be discussed in greater detail later in the consent form. Examples of model summary statements are available on the IRB website. Go to https://research.unc.edu/human-research-ethics/resources/common-rule/.	The revised Common Rule requires a Concise Summary section to present key information prior to the body of the consent document.
End of **"What will happen if you take part in the study?"**	N/A	**For Whole Genome Sequencing (WGS)**: A statement on whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). (may be omitted if not applicable)	The revised Common Rule requires subjects be informed when whole genome sequencing may be done on their research specimen.
Following "**What if we learn about new findings or information during the study?**"	N/A	**Will I receive any clinical results?** Clinically relevant results of this research will be communicated with you (describe which test results, when, and under what conditions). (if applicable).	The revised Common Rule requires subjects be informed of any clinically relevant results that will be communicated to subjects.

"**How will information about you be protected?"**	Participants will/will not be identified in any report or publication about this study.	Participants will/will not be identified in any report or publication about this study. **We may use de-identified data and/or specimens from this study in future research without additional consent.**	The revised Common Rule requires subjects be told that their de-identified data and/or specimens may be used for future research without additional consent or that the subject's information or biospecimens will not be used or distributed for future research studies even if identifiers are removed. The template adopts the more common option but may be revised but would restrict future use.
"**Will you receive results from research involving your specimens?"**	[Delete if separate consent for specimens] Most research with your specimens is not expected to yield new information that would be meaningful to share with you personally. There are no plans to re-contact you or other subjects with information about research results.	[Delete if separate consent for specimens] Most research with your specimens is not expected to yield new information that would be meaningful to share with you personally. There are no plans to re-contact you or other subjects with information about research results. **The use of your samples may result in commercial profit. You will not be compensated for the use of your samples other than what is described in this consent form.**	The revised Common Rule requires a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit. The template adopts the more common option. It may be revised if the researcher intends to share in commercial profit with the research subject(s).
Will you receive anything for being in this study?	Your name, address, and social security number (SSN) are required to	Your name, address, and **U.S. tax payer identification number (SSN or ITIN)** are required to process payments and/or to report taxable income to the IRS. **You must complete a W-9 (for U.S.**	This institution is updating language to better capture information

	process payments and/or to report taxable income to the IRS. You will be asked to sign a separate Social Security Number Collection form. If you do not provide your SSN (or ITIN), we cannot issue you a payment for participation. However, you may still choose to participate in this study.	**persons) or W-8BEN and the Foreign Vendor Withholding Assessment with supporting documents (for non-resident aliens) in order to receive payment for participation.** **U.S. person participants must complete Form W-9 in order to receive payment for participation. If payment by UNC equals or exceeds $600 per calendar year for U.S. persons, UNC will report the amount to the Internal Revenue Service on Form 1099. Nonresident alien participants must complete Form W-8BEN and the Foreign Vendor Withholding Assessment with supporting documents in order to receive payment for participation. Payments to nonresident alien participants may be subject to tax withholding and are generally reported to the Internal Revenue Service on Form 1042-S. This information will not be linked to any of the study data and will only be used for payment purposes.** If you do not provide your SSN or ITIN**, or complete the appropriate documentation noted above**, we cannot issue you a payment for participation. However, you may still choose to participate in this study."	regarding payment to research subjects.

Stored Specimens with Identifiers

Section	Previous	New	Rationale
Top of Header	N/A	IRB Template Version 2.0-12/5/2018 **DO NOT CHANGE THIS FIELD-IRB USE ONLY**	IRB template version has been added to facilitate review and tracking of consent document changes as IRB templates are updated.
Beginning of document, following the header	N/A	CONCISE SUMMARY The revised Common Rule requires that consent forms contain a concise presentation of key information. The intention of this section is to provide potential research participants with a better understanding of the project's scope, including major risks and benefits, so they can make a more fully informed decision about whether to participate. This section should include a summary of the purpose of the study, duration of participation, major requirements of the study and any potential benefits. This section should also contain any significant risks of participating in the study. The information presented in this section may be discussed in greater detail later in the consent form. Examples of model summary statements are available on the IRB website. Go to https://research.unc.edu/human-research-ethics/resources/common-rule/.	The revised Common Rule requires a Concise Summary section to present key information prior to the body of the consent document.
End of **"What will happen to the specimens?"**	N/A	**For Whole Genome Sequencing (WGS)**: A statement on whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). (may be omitted if not applicable)	The revised Common Rule requires subjects be informed when whole genome sequencing may be done on their research specimen.

Following "**Will you receive results from research involving your specimens ?**"	N/A	**Will I receive any other clinical results?** Other clinically relevant results of this research will be communicated with you (describe which test results, when, and under what conditions). (if applicable).	The revised Common Rule requires subjects be informed of any clinically relevant results that will be communicated to subjects.
"**Will researchers seek approval from you to do future studies involving the specimens** **"**	By signing this consent form, you are giving your permission for researchers to use your specimens as described above. Current and future research is overseen by a committee called the Institutional Review Board (IRB). The role of the IRB is to protect the rights and welfare of research participants. The IRB may require that you be re-contacted and asked for your consent to use your specimens in a specific research study.	By signing this consent form, you are giving your permission for researchers to use your specimens as described above. Current and future research is overseen by a committee called the Institutional Review Board (IRB). The role of the IRB is to protect the rights and welfare of research participants. **We may use de-identified data and/or specimens from this study in future research without additional consent. However, in some cases,** the IRB may require that you be re-contacted and asked for your consent to use your specimens in a specific research study.	The revised Common Rule requires subjects be told that their de-identified data and/or specimens may be used for future research without additional consent or that the subject's information or biospecimens will not be used or distributed for future research studies even if identifiers are removed. The template adopts the more common option but may be revised but would restrict future use.
"**Will you receive results from research involving your specimens?"**	[Delete if separate consent for specimens] Most research with your specimens is not expected to yield new information that would be meaningful to share with you personally. There are no plans to re-contact you or other subjects with information about research results.	[Delete if separate consent for specimens] Most research with your specimens is not expected to yield new information that would be meaningful to share with you personally. There are no plans to re-contact you or other subjects with information about research results. **The use of your samples may result in commercial profit. You will not be compensated for the use of your samples other than what is described in this consent form.**	The revised Common Rule requires a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit. The template adopts the more common option. It may be revised if the researcher intends to share

			in commercial profit with the research subject(s).

Information or Fact Sheet

Section	Previous	New	Rationale
Top of Header	N/A		IRB template version has been added to facilitate review and tracking of consent document changes as IRB templates are updated.
Beginning of document, following the header	N/A	CONCISE SUMMARY The revised Common Rule requires that consent forms contain a concise presentation of key information. The intention of this section is to provide potential research participants with a better understanding of the project's scope, including major risks and benefits, so they can make a more fully informed decision about whether to participate. This section should include a summary of the purpose of the study, duration of participation, major requirements of the study and any potential benefits. This section should also contain any significant risks of participating in the study. The information presented in this section may be discussed in greater detail later in the consent form. Examples of model summary statements are available on the IRB website. Go to https://research.unc.edu/human-research-ethics/resources/common-rule/.	The revised Common Rule requires a Concise Summary section to present key information prior to the body of the consent document.

End of **"What will happen to the specimens?"**	N/A	**For Whole Genome Sequencing (WGS)**: A statement on whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). (may be omitted if not applicable)	The revised Common Rule requires subjects be informed when whole genome sequencing may be done on their research specimen.
What are the possible risks or discomforts involved from being in this study?	N/A	The following sections were added: • What are the risks to a pregnancy or to a nursing child? • If you choose not to be in the study, what other treatment options do you have? • MRI and Gadolinium Risks associated with radiation exposure	Most studies obtaining consent using only an information sheet, will be minimal risk. Because of this, the information sheet template previously left out risk information only related to greater than minimal risk studies. However, there is a rare possibility that a greater than minimal risk study could receive a waiver of signed consent and use only an information sheet to obtain consent (i.e. the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality.)
Following "**Will you receive results from research involving your specimens**	N/A	**Will I receive any other clinical results?** Other clinically relevant results of this research will be communicated with you (describe which test results, when, and under what conditions). (if applicable).	The revised Common Rule requires subjects be informed of any clinically relevant results that will

?"			be communicated to subjects.
"**Will researchers seek approval from you to do future studies involving the specimens** **"**	By signing this consent form, you are giving your permission for researchers to use your specimens as described above. Current and future research is overseen by a committee called the Institutional Review Board (IRB). The role of the IRB is to protect the rights and welfare of research participants. The IRB may require that you be re-contacted and asked for your consent to use your specimens in a specific research study.	By signing this consent form, you are giving your permission for researchers to use your specimens as described above. Current and future research is overseen by a committee called the Institutional Review Board (IRB). The role of the IRB is to protect the rights and welfare of research participants. **We may use de-identified data and/or specimens from this study in future research without additional consent. However, in some cases,** the IRB may require that you be re-contacted and asked for your consent to use your specimens in a specific research study.	The revised Common Rule requires subjects be told that their de-identified data and/or specimens may be used for future research without additional consent or that the subject's information or biospecimens will not be used or distributed for future research studies even if identifiers are removed. The template adopts the more common option but may be revised but would restrict future use.
"**Will you receive results from research involving your specimens?"**	[Delete if separate consent for specimens] Most research with your specimens is not expected to yield new information that would be meaningful to share with you personally. There are no plans to re-contact you or other subjects with information about research results.	[Delete if separate consent for specimens] Most research with your specimens is not expected to yield new information that would be meaningful to share with you personally. There are no plans to re-contact you or other subjects with information about research results. **The use of your samples may result in commercial profit. You will not be compensated for the use of your samples other than what is described in this consent form.**	The revised Common Rule requires a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit. The template adopts the more common option. It may be revised if the researcher intends to share in commercial profit with the research subject(s).
Will you receive anything for being in this study?	Your name, address, and social security number (SSN) are required to	Your name, address, and **U.S. tax payer identification number (SSN or ITIN)** are required to process payments and/or to report	This institution is updating language to better capture information

	process payments and/or to report taxable income to the IRS. You will be asked to sign a separate Social Security Number Collection form. If you do not provide your SSN (or ITIN), we cannot issue you a payment for participation. However, you may still choose to participate in this study.	taxable income to the IRS. **You must complete a W-9 (for U.S. persons) or W-8BEN and the Foreign Vendor Withholding Assessment with supporting documents (for non-resident aliens) in order to receive payment for participation.** **U.S. person participants must complete Form W-9 in order to receive payment for participation. If payment by UNC equals or exceeds $600 per calendar year for U.S. persons, UNC will report the amount to the Internal Revenue Service on Form 1099. Nonresident alien participants must complete Form W-8BEN and the Foreign Vendor Withholding Assessment with supporting documents in order to receive payment for participation. Payments to nonresident alien participants may be subject to tax withholding and are generally reported to the Internal Revenue Service on Form 1042-S. This information will not be linked to any of the study data and will only be used for payment purposes.** If you do not provide your SSN or ITIN**, or complete the appropriate documentation noted above**, we cannot issue you a payment for participation. However, you may still choose to participate in this study."	regarding payment to research subjects.

Parental Permission Form

Section	Previous	New	Rationale
Top of Header	N/A	IRB Template Version 2.0-12/5/2018 **DO NOT CHANGE THIS FIELD-IRB USE ONLY**	IRB template version has been added to facilitate review and tracking of consent document changes as IRB templates are updated.
Beginning of document, following the header	N/A	CONCISE SUMMARY The revised Common Rule requires that consent forms contain a concise presentation of key information. The intention of this section is to provide potential research participants with a better understanding of the project's scope, including major risks and benefits, so they can make a more fully informed decision about whether to participate. This section should include a summary of the purpose of the study, duration of participation, major requirements of the study and any potential benefits. This section should also contain any significant risks of participating in the study. The information presented in this section may be discussed in greater detail later in the consent form. Examples of model summary statements are available on the IRB website. Go to https://research.unc.edu/human-research-ethics/resources/common-rule/.	The revised Common Rule requires a Concise Summary section to present key information prior to the body of the consent document.
End of **"What will happen if your child takes part in the study?"**	N/A	**For Whole Genome Sequencing (WGS)**: A statement on whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). (may be omitted if not applicable)	The revised Common Rule requires subjects be informed when whole genome sequencing may be done on their research specimen.
Following "**What if we learn**	N/A	**Will I receive any other clinical results?** Other clinically relevant results of this research will be communicated	The revised Common Rule requires subjects be

about new findings or information during the study?"		with you (describe which test results, when, and under what conditions). (if applicable).	informed of any clinically relevant results that will be communicated to subjects.
"**How will information about your child be protected?"**	Participants will/will not be identified in any report or publication about this study.	Participants will/will not be identified in any report or publication about this study. **We may use de-identified data and/or specimens from this study in future research without additional consent.**	The revised Common Rule requires subjects be told that their de-identified data and/or specimens may be used for future research without additional consent or that the subject's information or biospecimens will not be used or distributed for future research studies even if identifiers are removed. The template adopts the more common option but may be revised but would restrict future use.
"**Will you receive results from research involving your child's specimens?"**	[Delete if separate consent for specimens] Most research with your child's specimens is not expected to yield new information that would be meaningful to share with you or your child personally. There are no plans to re-contact you, your child, or other subjects with information about research results.	[Delete if separate consent for specimens] Most research with your child's specimens is not expected to yield new information that would be meaningful to share with you or your child personally. There are no plans to re-contact you, your child, or other subjects with information about research results. **The use of your child's samples may result in commercial profit. You or your child will not be compensated for the use of your child's samples other than what is described in this consent form**.	The revised Common Rule requires a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit. The template adopts the more common option. It may be revised if the researcher intends to share in commercial profit with the research subject(s).

Will you receive anything for being in this study?	Your name, address, and social security number (SSN) are required to process payments and/or to report taxable income to the IRS. You will be asked to sign a separate Social Security Number Collection form. If you do not provide your SSN (or ITIN), we cannot issue you a payment for participation. However, you may still choose to participate in this study.	Your name, address, and **U.S. tax payer identification number (SSN or ITIN)** are required to process payments and/or to report taxable income to the IRS. **You must complete a W-9 (for U.S. persons) or W-8BEN and the Foreign Vendor Withholding Assessment with supporting documents (for non-resident aliens) in order to receive payment for participation.** **U.S. person participants must complete Form W-9 in order to receive payment for participation. If payment by UNC equals or exceeds $600 per calendar year for U.S. persons, UNC will report the amount to the Internal Revenue Service on Form 1099. Nonresident alien participants must complete Form W-8BEN and the Foreign Vendor Withholding Assessment with supporting documents in order to receive payment for participation. Payments to nonresident alien participants may be subject to tax withholding and are generally reported to the Internal Revenue Service on Form 1042-S. This information will not be linked to any of the study data and will only be used for payment purposes.** If you do not provide your SSN or ITIN**, or complete the appropriate documentation noted above**, we cannot issue you a payment for participation. However, you may still choose to participate in this study."	This institution is updating language to better capture information regarding payment to research subjects.

Assent Form Ages 15-17

Section	Previous	New	Rationale
Top of Header	N/A	IRB Template Version 2.0-12/5/2018 **DO NOT CHANGE THIS FIELD-IRB USE ONLY**	IRB template version has been added to facilitate review and tracking of consent document changes as IRB templates are updated.
Beginning of document, following the header	N/A	CONCISE SUMMARY The revised Common Rule requires that consent forms contain a concise presentation of key information. The intention of this section is to provide potential research participants with a better understanding of the project's scope, including major risks and benefits, so they can make a more fully informed decision about whether to participate. This section should include a summary of the purpose of the study, duration of participation, major requirements of the study and any potential benefits. This section should also contain any significant risks of participating in the study. The information presented in this section may be discussed in greater detail later in the consent form. Examples of model summary statements are available on the IRB website. Go to https://research.unc.edu/human-research-ethics/resources/common-rule/.	The revised Common Rule requires a Concise Summary section to present key information prior to the body of the consent document.
End of **"What will happen if you take part in the study?"**	N/A	**For Whole Genome Sequencing (WGS)**: A statement on whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). (may be omitted if not applicable)	The revised Common Rule requires subjects be informed when whole genome sequencing may be done on their research specimen.

Following "**What if we learn about new findings or information during the study?**"	N/A	**Will I receive any clinical results?** Clinically relevant results of this research will be communicated with you (describe which test results, when, and under what conditions). (if applicable).	The revised Common Rule requires subjects be informed of any clinically relevant results that will be communicated to subjects.
"**How will information about you be protected?"**	Participants will/will not be identified in any report or publication about this study.	Participants will/will not be identified in any report or publication about this study. **We may use de-identified data and/or specimens from this study in future research without additional consent.**	The revised Common Rule requires subjects be told that their de-identified data and/or specimens may be used for future research without additional consent or that the subject's information or biospecimens will not be used or distributed for future research studies even if identifiers are removed. The template adopts the more common option but may be revised but would restrict future use.
"**Will you receive results from research involving your specimens?"**	[Delete if separate consent for specimens] Most research with your specimens is not expected to yield new information that would be meaningful to share with you personally. There are no plans to re-contact you or other subjects with information about research results.	[Delete if separate consent for specimens] Most research with your specimens is not expected to yield new information that would be meaningful to share with you personally. There are no plans to re-contact you or other subjects with information about research results. **The use of your samples may result in commercial profit. You will not be compensated for the use of your samples other than what is described in this consent form.**	The revised Common Rule requires a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit. The template adopts the more common option. It may be revised if the researcher intends to share

			in commercial profit with the research subject(s).
Will you receive anything for being in this study?	Your name, address, and social security number (SSN) are required to process payments and/or to report taxable income to the IRS. You will be asked to sign a separate Social Security Number Collection form. If you do not provide your SSN (or ITIN), we cannot issue you a payment for participation. However, you may still choose to participate in this study.	Your name, address, and **U.S. tax payer identification number (SSN or ITIN)** are required to process payments and/or to report taxable income to the IRS. **You must complete a W-9 (for U.S. persons) or W-8BEN and the Foreign Vendor Withholding Assessment with supporting documents (for non-resident aliens) in order to receive payment for participation.** **U.S. person participants must complete Form W-9 in order to receive payment for participation. If payment by UNC equals or exceeds $600 per calendar year for U.S. persons, UNC will report the amount to the Internal Revenue Service on Form 1099. Nonresident alien participants must complete Form W-8BEN and the Foreign Vendor Withholding Assessment with supporting documents in order to receive payment for participation. Payments to nonresident alien participants may be subject to tax withholding and are generally reported to the Internal Revenue Service on Form 1042-S. This information will not be linked to any of the study data and will only be used for payment purposes.** If you do not provide your SSN or ITIN**, or complete the appropriate documentation noted above**, we cannot issue you a payment for participation. However, you may still choose to participate in this study."	This institution is updating language to better capture information regarding payment to research subjects.

Consent addendum

Section	Previous	New	Rationale
Top of Header	N/A	IRB Template Version 2.0-12/5/2018 **DO NOT CHANGE THIS FIELD-IRB USE ONLY**	IRB template version has been added to facilitate review and tracking of consent document changes as IRB templates are updated.

Short form

Section	Previous	New	Rationale
Top of Header	N/A	IRB Template Version 2.0-12/5/2018 **DO NOT CHANGE THIS FIELD-IRB USE ONLY**	IRB template version has been added to facilitate review and tracking of consent document changes as IRB templates are updated.

Assent Form Ages 14-17

Section	Previous	New	Rationale
Top of Header	N/A	IRB Template Version 2.0-12/5/2018 **DO NOT CHANGE THIS FIELD-IRB USE ONLY**	IRB template version has been added to facilitate review and tracking of consent document changes as IRB templates are updated.