

Template Language for the Four New Consent Elements under the 2018 Common Rule

Consent and Assent templates are available at https://research.vcu.edu/forms/index.htm#irb_forms

INSTRUCTIONS: Insert the language of either Option A or Option B into the **Procedures section if the study will collect biospecimens**. Language may be modified as appropriate.

Additional element of consent 46.116(c)(9): “For research involving biospecimens, 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).”

If there is any chance that whole genome sequencing (i.e. sequencing of a human germline or somatic specimen with the intent to generate the genome or exome of that specimen) could be done in this study or future research studies, insert Option A.

[Option A – Studies that **will or might** perform whole genome sequencing, insert:] This study **will or might** use your samples to sequence all or part of your DNA.

Deoxyribonucleic acid (DNA) is the “blueprint” or “recipe” that gives the body’s cells instructions on how to do their jobs. Scientists can use a test called whole genome sequencing to determine the order of all or part of the molecules that make up your DNA, like reading all the letters in a book. Sequencing is usually done to look for changes in the molecules of DNA that may cause health problems.

[Option B – Studies that **will not** perform whole genome sequencing, insert:] This study will not use your samples to sequence all or part of your DNA.

INSTRUCTIONS: Insert the following language into the **Confidentiality section for all studies**. Language may be modified as appropriate.

Additional element of consent 46.116(c)(8): “A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions”

In general, we will not give you any individual results from the study. **[Insert if the study may have clinically relevant findings:]** If we find something of medical importance to you, we will inform you, **[or explain another method of communicating the information]** although we expect that this will be a very rare occurrence. **[Insert if participants will receive aggregate study results:]** Once the study has been completed, we will send you a summary of all of the results of the study and what they mean.

INSTRUCTIONS: Insert the following language into the **Confidentiality section if the study will collect biospecimens**. Modifications to the language are not recommended

Additional element of consent 46.116(c)(7): “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”

There are no plans to share any money or profits with you if the use of your sample(s) results in inventions or discoveries that have commercial value. [Or, if the participant will share in profits, revise to give an explanation of the commercial profit that would/will be given to the participant.]

INSTRUCTIONS: Insert the language of either Option A or Option B into the **Confidentiality section for all studies with identifiable or de-identified information or specimens** (i.e. studies that do not collect completely anonymous data and/or specimens). Modifications to the language are not recommended.

Basic element of consent 46.116(b)(9): “One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.”

If there is any chance that information or biospecimens could be used in future studies, insert Option A.

[Option A – Studies that will or might use information or biospecimens for future research

studies, insert:] In the future, identifiers might be removed from the information and samples you provide in this study, and after that removal, the information/samples could be used for other research studies by this study team or another researcher without asking you for additional consent.

[Option B – Studies that will not use information or biospecimens for future research studies,

insert:] The information and samples collected as part of this study will not be used or distributed for future research studies, even if identifiers are removed.