





A division of BRANY 

# Secondary Research Under the Final Rule: New Consent Form Language Requirements with Examples

 Required Consent Statement per 46.116(b)(9)	Example Consent Language
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 (46.116[b][9][i]).	<i>Any personal information that could identify you will be removed from your sample. Your sample may be used for future research studies without the investigator asking for your additional permission.</i>
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 (46.116[b][9][ii]).	<i>Any personal information that could identify you will be removed from your sample. Your sample will not be used for any future research studies.</i>

 Additional Elements of Informed Consent per 46.116(c)	Example Consent Language
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 (46.116[c][7]).	<i>Your sample may be used to develop new drugs or other products for commercial purposes. If these products make money there are no plans to share the money with you.</i>
A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions (46.116[c][8]).	<i>Example 1 - Results of research testing on your sample will be returned to you.</i>  <i>Example 2 - Results of research testing on your sample may be given to you or your doctor. This will be done only if the results may be necessary for your care.</i>
For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (in other words, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen) (46.116[c][9]).	<i>Research testing on your sample will include whole genome sequencing. This means we will map your entire genetic code. If you have questions about this ask the study staff.</i>