

## Proposed revisions to informed consent under the NPRM

Basic Elements of Informed Consent	Elements of Broad Consent
<p>All elements previously required <b>and</b> 4 new elements, when appropriate:</p>	<p>Some basic elements from section .116 of the NPRM [a(2),3,5, and 7 and, if applicable, (b)(7-9)] <b>and</b>:</p>
<ul style="list-style-type: none"> <li>• A statement to inform participants that either their data may be stripped of identifiers and used for secondary research or that the data collected will not be used for future research</li> <li>• A statement that the biospecimens may be used for commercial profit and whether or not the subject will share in profit</li> <li>• A statement on whether clinically relevant research results will be disclosed to subjects and under what conditions</li> <li>• An option to consent or refuse to consent to re-contact by investigators for additional information or biospecimens or to discuss participation in another study</li> </ul>	<ul style="list-style-type: none"> <li>• A description of scope– what will be collected and for how long</li> <li>• A description of how long biospecimens and information will be available for secondary research</li> <li>• A statement that participation is voluntary, refusal to participate involves no loss of benefit, and participant may withdraw consent</li> <li>• If applicable, a statement that the participant will not be given specific details about the use of his/her biospecimens and information</li> <li>• A general description of types of research that may be conducted</li> <li>• The names of the institution(s) where biospecimens and information will be collected</li> <li>• If relevant, an option to consent or refuse to consent to inclusion of de-identified data in a publically-accessible database</li> </ul>