**Informed Consent Guidance: Required and Additional Elements for Revised Common Rule (RCR)**

1. **Verify that the *informed consent process* meets each of the general requirements (45 CFR 46.116a). Note that these elements cannot be waived. The Primary Reviewer will address the items in gray in the Reviewer Form.**

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| **Item #**  | **ITEMS** |
|  | *NEW ELEMENTS:* **GENERAL REQUIREMENTS** |
| **1** | Consents/assents for all subjects or subject/s LAR except those for whom consent is waived |
| **2** | Consent will be obtained under circumstances that minimize the possibility of coercion or undue influence |
| **3** | Consent will be given in a language understandable to the subject or LAR |
| **4** | Consent includes information that a reasonable person would want to have in order to make an informed decision |
| **5i** | Consent begins with a concise and focused presentation of the information that is most likely to assist a subject in understanding why s/he might or might not want to participate |
| **5ii** | Consent must be organized and presented in a way that does not merely provide lists of isolated facts.  |
| **6** | Consent does not include exculpatory language through which the subject is made to waive legal rights.  |

1. **Verify that the informed consent document contains each of the basic elements of informed consent (45 CFR 46.116b)**

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| **Item #**  | **BASIC ELEMENTS (when applicable)** |
| **1a** | a statement that the study involves research, and |
| **1b** | an explanation of the purposes of the research, and |
| **1c** | the expected duration of the participant ‘s participation, and |
| **1d** | a description of the procedures to be followed, and  |
| **1e** | identification of any procedures which are experimental; |
| **2** | a description of any reasonably foreseeable risks or discomforts to the participant; |
| **3** | a description of any benefits to the participant or to others which may reasonably be expected from the research |
| **4** | a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant; |
| **5a** | a statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained; and |
| **5b** | if the research is subject to Food and Drug Administration (FDA) regulation, a statement that notes the possibility that FDA may inspect the records  |
| **6a** | for research involving more than minimal risk, an explanation as to whether any compensation is available if injury occurs, and |
| **6b** | an explanation as to whether any medical treatments are available if injury occurs and,  |
| **6c** | if so, what they consist of, or where further information may be obtained; |
| **7a** | an explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and  |
| **7b** | whom to contact in the event of a research-related injury to the participant; |
| **8a** | a statement that participation is voluntary, and |
| **8b** | a statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and |
| **8c** | a statement that the participant may discontinue participation at any time withoutpenalty or loss of benefits to which the participant is otherwise entitled. |
| **9** | *NEW ELEMENT*: One of the following statements about research that involves the collection of identifiable private information or identifiable biospecimens:1. A statement that identifiers might be removed from the information or biospecimens and that, after such removal, the information or specimens could be used for future research studies or distributed to another investigator for future studies without additional informed consent being obtained.
2. A statement that the information or biospecimens, even if identifiers are removed, will not be used or distributed for future research studies.
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1. **Verify that where appropriate, one or more of the following additional elements of information is provided in the consent form (45CFR46.116c).**

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| **Item #**  | **ADDITIONAL ELEMENTS** |
| 1a | a statement that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable; and |
| 1b | if the participant is or may become pregnant, a statement that the particular treatment or procedure may involve risks to the embryo or fetus which are currently unforeseeable; |
| 2 | anticipated circumstances under which the participant’s participation may be terminated by the investigator without regard to the participant’s consent; |
| 3 | any additional costs to the participant that may result from participation in the research;  |
| 4a | the consequences of a participant’s decision to withdraw from the research;  |
| 4b | the process for an orderly withdrawal from a study; |
| 5 | a statement that significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation will be provided to the participant; |
| 6 | the approximate number of participants involved in the study;  |
| 7a | *NEW ELEMENT*: A statement that the subject’s biospecimens may be used for commercial profit; |
| 7b | *NEW ELEMENT:* A statement about whether the subject will or will not share in the commercial profit; |
| 8 | *NEW ELEMENT*: A statement about whether clinically relevant results will be disclosed to the subject; |
| 9 | *NEW ELEMENT:*  A statement about whether the research will, or might (if known), include whole genome sequencing. |

1. **In addition to the required elements, the following must be included, if applicable:**

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| **Yes** | **NA** | **Other Mandatory Consent Provisions, if applicable** |
|  |  | Individual or Institutional Conflict of Interest |
|  |  | HIPAA Authorization |
|  |  | Registration on Clinicaltrials.gov |
|  |  | Genomic Data Sharing Policy language |
|  |  | Certificate of Confidentiality language for NIH funded studies. |