**HQ USAMRMC INSTITUTIONAL REVIEW BOARD OFFICE GUIDANCE**

**Revised Common Rule: Additional Required Protocol Information**

Section B5.1: If the research involves assigning participants prospectively to one or more interventions, is designed to evaluate the effect of the intervention(s) on the participants, and the effect being evaluated is a biomedical or behavioral health-related outcome, identify the research study as a clinical trial.

Section B5.6: Explain whether or not data and / or biospecimens collected for the research will / may be used in future research.

* If future research is probable, specify the type of future research for which the data / specimens will be used (e.g., human performance research). If the type of research is not specific, state this.
* Explain the provisions that will be put in place for maintaining confidentiality of data / biospecimens stored for future research.
* If identifiable private information or identifiable biospecimens are maintained, add information stating that **either**:
	+ 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; **or**
	+ Identifiers might be removed from the subject’s information or biospecimens and, after removal, the information or biospecimens could be 1) used for future research studies or 2) distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative.

Section C1.3: If an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, explain how eligibility information will be obtained, e.g. through oral or written communication with the prospective subject or the legally authorized representative; accessing identifiable private information from medical records; accessing stored identifiable biospecimens.

Section C1.4: Address, as applicable, that documentation of informed consent will / may be captured in the form of an electronic signature. Explain the plan for providing subjects / LARs a copy of the consent form.

* If the research is a clinical trial (see above), include a statement that the IRB-approved consent form used to enroll subjects will be posted on a publically available federal website (PLEASE NOTE that we are awaiting further guidance) after the trial is closed to enrollment, but no later than 60 days after the last study visit by any subject.

Section C1.4.3: Address how the research could not be practicably carried out without access to or use of private identifiable information or identifiable biospecimens.

Section C1.4.4: If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, add information that the research presents no more than minimal risk of harm to subjects and that there is an appropriate alternative mechanism for documenting that informed consent was obtained.

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**Revised Common Rule: Additional Required Protocol Information (Continued)**

Section C5: If a key linking subjects’ name to study code will be utilized, describe the plan for maintaining it, i.e. what format will be used, who will have access to it, where it will be stored, and when it will be destroyed.

Section 6.2: State whether or not clinically relevant research results (including individual research results) will be disclosed to the subject and under what condition(s).