DEPARTMENT OF THE ARMY
HEADQUARTERS, U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
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FCMR-RP

MEMORANDUM FOR RECORD

SUBJECT: Clarification of Office of Research Protections (ORP) oversight of the use of existing, established PDX models in USAMRDC supported research.

1. References:

a. Memorandum, SECARMY, 5 November 2019, subject: Army Policy for Use of Human Cadavers for Research, Development, Test and Evaluation, Education or Training.

b. Guidance on HRPO Review Requirements for Research Involving the Secondary Use of Data/Specimens, 8 May 2020

2. This memorandum serves to clarify that USAMRDC supported research involving the use of established, existing patient derived xenograft (PDX) models (or the cell lines derived therein) that were established using tissue from deceased donors does not require ORP Human Research Protection Office's review and oversight for cadaver use in accordance with reference (a).

3. HRPO submission and review remains required when DoD funding is used to combine human specimens (e.g. cell lines, tissue) with non-human material to create a xenograft for research use in accordance with reference (b). In addition, the use of established, existing PDX models established using tissue from living donors and/or the creation of cell lines from established, existing PDX models currently does not require MRDC HRPO review.

4. The research use of established, existing PDX models created without DoD support (e.g., research with mice) does require institutional animal use and USAMRDC ORP Animal Care and Use Review Office (ACURO) review.

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