8. RESEARCH MONITOR

a. For DoD-conducted research involving human subjects determined by the IRB to involve more than minimal risk to human subjects (as defined in section 219.102(i) of Reference (c)), and, to the extent provided pursuant to Parts 22 (Appendix B), 37 (Appendix D), and 219 of Reference (c) and Reference (o), comparable DoD-supported research, the IRB shall approve an independent research monitor by name. Additionally, the research monitor may be identified by an investigator or appointed by an IRB or IO for research involving human subjects determined to involve minimal risk. There may be more than one research monitor (e.g., if different skills or experiences are necessary). The monitor may be an ombudsman or a member of the data safety monitoring board.

(1) The duties of the research monitor shall be determined on the basis of specific risks or concerns about the research. The research monitor may perform oversight functions (e.g., observe recruitment, enrollment procedures, and the consent process for individuals, groups or units; oversee study interventions and interactions; review monitoring plans and UPIRTSO reports; and oversee data matching, data collection, and analysis) and report their observations and findings to the IRB or a designated official.

(2) The research monitor may discuss the research protocol with the investigators, interview human subjects, and consult with others outside of the study about the research. The research monitor shall have authority to stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor’s report. Research monitors shall have the responsibility to promptly report their observations and findings to the IRB or other designated official.

(3) The IRB must approve a written summary of the monitors’ duties, authorities, and responsibilities. The IRB or HRPP official shall communicate with research monitors to confirm their duties, authorities, and responsibilities.

(4) The research monitors shall have expertise consonant with the nature of risk(s) identified within the research protocol, and they shall be independent of the team conducting the research involving human subjects.