

Are DOD personnel “engaged” in research or study participants?

Yes, study is considered “intramural” and must be reviewed by site’s IRB, DOD IRB, then HRPO

If data is “DoD owned” then cloud storage not allowed unless approved by DOD.

USAF only personnel must take CITI training every year.

No, study is considered “extramural” and must be reviewed by site’s IRB then HRPO

Is study minimal risk or greater than minimal risk?

Minimal risk- no further review required. LAR allowed for blood draws and data collection.

If intramural and greater than minimal risk, must also be reviewed by SG. This review can take several months.

Greater than minimal risk- participant must consent (No LAR, waiver of consent) unless direct benefit to subject. Secretary of DOD or designee may approve waiver of consent in greater than minimal risk studies.