

Given the unprecedented effects upon business operations in general due to the COVID19 pandemic, we foresee impact to AF-supported HRPO-approved research.

1. **AMENDMENTS.** Per the existing terms of your HRPO approved studies, any substantive amendment requires HRPO review and approval prior to implementation. **The HRPO will not require pre-approval, however, of any amendments intended to minimize the risk of COVID-19 exposure for research volunteers or study team members.** Accordingly, researchers must follow their local institution's guidance or requirements for IRB review and approval of amendments. As soon as possible, submit substantive amendments [and all relevant documentation in support thereof] to [usaf.pentagon.af-sg.mbx.afmsa-sge-c@mail.mil](mailto:usaf.pentagon.af-sg.mbx.afmsa-sge-c@mail.mil).

2. **UPIRTSOs.** Per the terms of your HRPO approval, which is governed by 32 CFR Section 219, "The Common Rule", when it comes to Unanticipated Problems Involving Risks to Subjects or Others, "UPIRTSOs" must be promptly reported. By definition, any UPIRTSO [whether related to the COVID-19 pandemic or not], include: inadvertent exposure of research subjects and/or study personnel, missed or delayed safety assessments, inability to provide study product or substantive research intervention. Again, UPIRTSOs in general and COVID-19 pandemic matters in particular, are to be promptly reported to the reviewing IRB. Additionally, UPIRTSOs are also reportable to HRPO via our standard E-Mail address: [usaf.pentagon.af-sg.mbx.afmsa-sge-c@mail.mil](mailto:usaf.pentagon.af-sg.mbx.afmsa-sge-c@mail.mil).

3. **HALTING A STUDY.** Promptly report any action that triggers a halt to ongoing HRPO-approved human subjects research, e.g., a pause to new enrollment or cessation of follow-up procedures with previously enrolled subjects. In short, if related to the COVID-19 pandemic, the local IRB should be notified and in turn, report these matters to our HRPO E-Mail address: [usaf.pentagon.af-sg.mbx.afmsa-sge-c@mail.mil](mailto:usaf.pentagon.af-sg.mbx.afmsa-sge-c@mail.mil).

**ACTION.** Whether it is a COVID-19 issue today, a separate matter next month, issues affecting a planned or ongoing HRPO-related study can always be discussed with HRPO by calling 703 681- 6147 / 8056/6277/ 8160 or by email at [usaf.pentagon.af-sg.mbx.afmsa-sge-c@mail.mil](mailto:usaf.pentagon.af-sg.mbx.afmsa-sge-c@mail.mil).