

The following are a set of recommendations for the FPU research community, in addressing some issues in IRB protocols in light of the recent pandemic, and during the COVID-19 shelter in place orders and stay at home situations.

### How to address:

#### **In-person studies/surveys.**

- Consider use of digital technology as a substitute for in-person visits or in-person surveys/procedures that do not impact the integrity of the study or participant safety as a viable alternative. This can include virtual visits, or online surveys through shared links.

#### **Low enrollment in studies.**

- If, at the time of continuing review, some studies appear to not be meeting enrollment goals due to COVID-19 outbreak-related issues, consider detailing the impact of this outbreak on the study in the continuing review report.

#### **Monitoring participants.**

- Remote monitoring is a suitable alternative to monitoring participants at a site. Email, video conferencing and secure file transfer can facilitate this process.

#### **Research participants with possible exposure.**

- FPU IRB recommends all studies include a brief survey screening the participant for possible exposure before participants report for any study-related visits and in-person interactions. Participants with possible exposure or symptoms of illness should be scheduled/re-scheduled for a future date.

#### **Changes to IRB still require IRB notification.**

- Investigators are permitted to implement study changes to “*eliminate apparent immediate hazards to the subject* (see the electronic code of federal regulations, protection of human subjects under 45 CFR 46.108[a][3][iii] and 21 CFR 56.109[a] for details).” If changes are made: those changes still need to be reported promptly to the IRB at IRB@fresno.edu.

To remain current on any changes in practice required, please refer to FPU’s COVID-19 Guidance for the community daily.