Changes to Research Made in Response to COVID-19

The Office of Human Research (OHR) anticipates the need for investigators to make changes to clinical studies in response to the current COVID-19 epidemic. These changes may include:

- Decreasing the number of protocol-mandated in-person study visits to healthcare facilities
- Replacing protocol-mandated visits to healthcare facilities with home visits or telemedicine
- Allowing blood draws at remote or commercial laboratories
- Shipping investigational products directly to research participants

Following is guidance for IRB review of changes in research made in response to this situation.

The FDA regulations require that:

Each IRB shall: (a) Follow written procedures for ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval **except where necessary to eliminate apparent immediate hazards to the human subjects.** 21 CFR 56.108(a)(4).

If a sponsor or investigator needs to make a change to research plans in order to eliminate apparent immediate hazards to research participants, these changes can be made and enacted immediately and then reported to OHR. Eliminating immediate hazards may include actions to reduce potential exposure to COVID-19, or to continue to provide medically necessary study care (including study drug) to participants who have been placed in isolation or quarantine because of suspected or known exposures. OHR supports necessary steps taken to eliminate apparent immediate additional risks to participants.

The notification to the IRB should be made via the eazUP electronic reporting system accessible on the IRB website. If you cannot access the system, please send email notification to kyle.conner@jefferson.edu. The report/memo should explain the changes being made in study procedures, provide assessment of the relative risks resulting from the changes, and indicate the expected duration of the changes. OHR staff will then determine whether a formal amendment will need to be submitted to the IRB.

Please contact OHR at 215-503-8966 with questions about this procedure.