Please review these common *Examples* of when to submit an *Amendment* to the IRB, given current COVID-19 considerations:

1) **Example 1:** The study team would like to add a few questions to their survey/focus group instruments related to influences due to COVID; these questions are not the institutionally mandated screening questions.

   This would require an amendment as the study team is collecting additional information for research purposes.

   COVID screening questions are not collected for research purposes and are institutionally required. If, however, the study team is proposing retaining the answers of the screening questions as part of the research study, this would require an amendment as it changes the scope of the approved research.

2) **Example 2:** The study team would like to move from in-person visits gathering carbon monoxide readings to using a mobile app that will collect the readings.

   This would require an amendment. Moving from collection of in-person readings to the use of a mobile app is not a "change in platform", as the app here would be considered a mobile medical app and therefore subject to FDA regulations. The change in collection here is a change in devices used for the study and requires IRB review and approval.

3) **Example 3:** The study team would like to eliminate the urine pregnancy test from screening procedures (likely because this would involve an in-person visit) for eligibility.

   This would require an amendment in that the removal of pregnancy testing goes to the risk mitigation for enrollment in the study.

4) **Example 4:** Does the discontinuation at Duke of non-essential research mean that Duke IRB approved protocols for coordinating centers have to stop seeing participants at other institutions?

   Generally, the Duke teams will need to coordinate with the local sites and determine the best course of action for the individual study. They will need to take into account whether there is a single IRB of record or multiple IRBs with oversight of specific aspects/sites, how coordinating center activities impact the ongoing conduct of the study at participating sites, and "local context". Local

context here is referring to state, municipal, institutional, and IRB policies in place.

For example, what may be permissible in Wisconsin may not be permissible in Illinois. Additionally, many major academic institutions have issued guidance on continuing conduct of research at those institutions.

Duke faculty and staff will need to comply with our local context rules, and then coordinate how that impacts the research on a study-by-study basis.

5) **Example 5:** The study team would like to modify the recruitment process so that the study team can send directed messages/recruitment via MyChart. Recruitment through MyChart was not previously anticipated.

This would require an amendment as it is a change to the recruitment strategy and possibly to the recruitment materials. As IRBs are charged with approving recruitment designs and recruitment materials, such a change to directed emails via MyChart requires IRB approval.