To: researchers involved in approved Human Subjects Research

Reminder – § 45 CFR 46.108 and §21 CFR 56.108(a)(4) require that each IRB shall....“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 human subjects.”

If an investigator needs to change research plans in order to eliminate apparent immediate hazards to research participants, these changes can be made and then reported to the UW IRB within 5 business days. Eliminating immediate hazards may include actions to reduce potential exposure to COVID-19 such as: decreasing the number of protocol-mandated in-person study visits or moving to remote study/teleconferencing study visits; delaying study visits to outside the study defined schedule to ensure participants are not traveling unnecessarily; among other options.

If your project received an Expedited or Full Board APPROVAL: Submit a Protocol Update Form.
Given these unique circumstances, the IRB will accept amendments to document these changes after implementation. Any documentation submitted will proceed with IRB review as per the usual process.

If your project received an Exempt DETERMINATION: Document for your own records.
Under this circumstance you are not required to submit a protocol update form to document a change from in-person to virtual participant interactions or delaying/altering study visits to outside the defined schedule. Instead, please save a copy of this notification along with a brief overview of your protocol changes for your own records. The IRB may ask for your documentation with future renewals or amendments. If changes fall outside of the parameters outlined here, submit a protocol update form as described above.

How do I tell if I received an Expedited or Full Board APPROVAL or an Exempt DETERMINATION?
• Please review your approval letter language.

Special Circumstance: If you received an exempt determination and are currently recruiting from SONA or Qualtrics and need to change your recruitment method, population, or compensation, you do not need to submit a protocol update form. Please update all relevant documents to include the updated information (recruitment, consent, etc.). Save a copy of this notification along with a brief overview of your protocol changes for your own records.
Examples:
   1. I am currently recruiting from SONA for an in-person experiment. Since students will not be on campus, can I change my recruitment pool to a different participant pool?
YES. Although this does not clearly align with the allowances “to eliminate apparent immediate hazards to human subjects,” if the participants voluntarily choose to participate this is still considered everyday living risk.

2. I am currently recruiting from SONA for an online experiment. Since students will not be on campus, I anticipate that I will not get the same amount of enrollment. Can I change my recruitment pool to a different online platform (Qualtrics, etc.) and offer monetary compensation instead of research credit? YES. The change of recruitment pool and compensation method will not alter the risk to participants.