Coronavirus and Research

Given the current COVID-19 outbreak, investigators should consider whether at any point their research procedures should be revised to limit personal contacts, for example by reducing the frequency of in-person visits or replacing in-person interviews with telephone or Internet contacts. Whether and when this may be advisable will vary depending on your protocol and the subjects with whom you are working.

We want to remind you that while the federal regulations that guide our oversight of research require that we review revisions to protocol before they are implemented, there is one important exception, “where necessary to eliminate apparent immediate hazards to the human subjects.” 21 CFR 56.108(a)(4).

Should you determine that changes in your procedures are required, you can implement them immediately, without prior notice to or approval from the IRB. You will need to ensure that you are not introducing other risks, and you may need to ask subjects to sign revised informed consent forms. All changes should be reported to the IRB via email within 48 hours, and a protocol modification form should be submitted to the IRB within 5 business days. Please include copies of any new or revised subject-facing materials with the changes clearly highlighted in both the email and protocol modification form.

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