COVID 19: Guidance for Conducting Human Subjects Research

Version 2, February, 2022

In addition to this plan, the Guidance for Clinical Trial Research & COVID 19 must be followed, as applicable, which provides general requirements and considerations with respect to patients enrolled, or being considered for enrollment and the management of USA Health Clinical Trials.

Minimum Requirements for Human Subjects Research:

- Lower-risk human subjects' activities may be allowed. The preference is for remote interactions whenever possible, for safety.
- If activities are approved by the IRB to be conducted in person, additional precautions to protect both research teams and subjects may be sought.
    - If procedures require less than 6ft of distance, the researcher may take additional precautions including wearing masks and use of other personal protective equipment. NOTE: The use of face coverings on the USA main campus is an individual option, at the discretion for each member of the study team and individual participants.
    - Schedule appointments to not overlap with other subjects
    - Research areas/equipment must be sanitized between subject visits.
    - Research personnel must follow USA's (on-campus/healthcare systems) mask policy and offer/provide masks for participants.
    - For individual contact tracing purposes, maintain a list of all subjects who come on-site and who interacted with them.
- Online Zoom platform
    - Online interviews that require HIPAA or other healthcare privacy compliance must utilize the USA Health Systems HIPAA-compliant ZOOM portal.

Engagement in the following activities:

- In person focus groups may continue. For focus group sessions, seating should be spaced out.
- IRB protocols transitioning to online methodologies (highly encouraged) is permissible after IRB review and approval.
- Research conducted in external clinics/other institutional settings such as schools, prisons, community settings is permissible, providing that the external site allow such engagement during the pandemic and the researcher follows applicable safety protocols.
- If you have an IRB protocol that requires the testing of human subjects for research purposes with an FDA approved COVID-19 test, both positive and negative cases must be reported to state/local health authorities. This must be disclosed in the consent form.
- The IRB must be notified and approve change in practices from the originally approved protocol prior to engagement in activities

USA IRB:

- The USA IRB will continue to consider the risk/benefit ratio during pandemic health waves for subject's participating in research.

- Currently an Archived Guidance: See IRB Review and Research Guidance COVID 19, March 12, 2020 for when and how the IRB must be notified of changes to approved research and other regulatory activities.

USA Main Campus:

- University of South Alabama COVID-19 Response Team continues to reassess policies and updates them accordingly. See Updates on Coronavirus

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