1. If one or more of my study subjects is isolated or quarantined for COVID-19 or tests positive for COVID-19 subsequent to taking part in a study activity, what should I do?

**ANSWER:** IF THE SUBJECT IS UNDER ISOLATION OR TESTS POSITIVE FOR COVID-19, ALL STUDY ACTIVITIES INVOLVING ANY INTERACTION OR INTERVENTION WITH OR BETWEEN STUDY SUBJECTS AND/OR STUDY STAFF MUST IMMEDIATELY CEASE in order to protect study subjects, members of the study team and others. The study must be suspended. All other FSU-mandated precautions or requirements must be implemented. If cessation of study activities may present risk of harm to any subject’s health and safety (e.g., abrupt cessation of study-related clinical treatment), then arrangements must be made by the study team to ensure necessary clinical care of such study subjects outside of the study, such as continued availability of study drugs or clinical follow-up. Researchers must: (1) promptly notify the IRB about any study subject that is isolated or tests positive for COVID-19 subsequent to taking part in any study-related interaction or intervention; (2) promptly notify by widest possible dissemination all previously-enrolled subjects, study sites and all study staff that one or more study subjects has been isolated or tested positive for COVID-19 subsequent to taking part in study-related interaction or intervention; and (3) promptly notify the IRB of the suspension of the study, cessation of all interaction and/or intervention between study subjects, between subjects and study staff, and between staff, and provide documentation of the notice to previously-enrolled subjects and study staff. The IRB will review the steps taken by the study team to ensure the orderly cessation of study activities to ensure the continuing safety of all study subjects, the study suspension, and may take other action deemed necessary to protect others against unanticipated risks. The IRB may permit study data collected to the point of a subject’s withdrawal to be retained.

IF THE SUBJECT IS QUARANTINED FOR OR IS OTHERWISE REASONABLY BELIEVED TO HAVE BEEN EXPOSED TO COVID-19 BUT ARE NOT YET SYMPTOMATIC, ALL STUDY ACTIVITIES MUST BE CAREFULLY EVALUATED TO MINIMIZE RISKS TO STUDY SUBJECTS AND STUDY STAFF. Consider ceasing any interaction or intervention with or between study subjects and/or study staff until authoritative information including any updates about the possible COVID-19 risks to subjects and staff is obtained. Researchers must: (1) promptly notify the IRB about any study subject that is quarantined for or is otherwise reasonably believed to have been exposed to COVID-19 subsequent to taking part in any study-related interaction or intervention; (2) promptly notify by widest possible dissemination all previously-enrolled subjects, study sites and all study staff that one or more study subjects has been quarantined for or is reasonably believed to have been exposed to COVID-19 subsequent to taking part in study-related interaction or intervention; and (3) promptly notify the IRB of the incident, steps taken to obtain authoritative information about possible COVID-19 risks to
study subjects and study staff suspension of the study, rationale for continuing interaction and/or intervention between study subjects, between subjects and study staff, and between staff, and provide documentation of the notice to previously-enrolled subjects and study staff. The IRB will review the steps taken by the study team to ensure the orderly cessation of study activities to ensure the continuing safety of all study subjects, the study suspension, and may take other action deemed necessary to protect others against unanticipated risks. The IRB may permit study data collected to the point of a subject’s withdrawal to be retained.

2. What will the IRB require if I or a study team member is required to be isolated or quarantined for COVID-19, tests positive for COVID-19, or has otherwise been exposed to COVID-19 prior to or at the time of any study-related interaction or intervention involving study subjects and/or study staff?

**ANSWER:** ALL STUDY ACTIVITIES INVOLVING ANY INTERACTION OR INTERVENTION WITH OR BETWEEN STUDY SUBJECTS AND/OR STUDY STAFF MUST IMMEDIATELY CEASE in order to protect study subjects, members of the study team and others. The study must be suspended. All other FSU-mandated precautions or requirements must be implemented. If cessation of study activities may present risk of harm to any subject’s health and safety (e.g., abrupt cessation of study-related clinical treatment), then arrangements must be made by the study team to ensure necessary clinical care of such study subjects outside of the study, such as continued availability of study drugs or clinical follow-up. Researchers must: (1) promptly notify the IRB about any study member (including the Principal Investigator) that is isolated or quarantined for COVID-19, tests positive for COVID-19, or has otherwise been exposed to COVID-19 prior to or at the time of any study-related interaction or intervention involving study subjects and/or study staff; (2) promptly notify by widest possible dissemination all previously-enrolled subjects and all study staff that one or more study staff has been isolated or quarantined for COVID-19, tested positive for COVID-19, or has otherwise been exposed to COVID-19 prior to or at the time the study staff has taken part in study-related interaction or intervention involving study subjects and/or study staff; and (3) promptly notify the IRB of the suspension of the study, cessation of all interaction and/or intervention between study subjects, between subjects and study staff, and between staff, and provide documentation of the notice to previously-enrolled subjects and study staff. The IRB will review the steps taken by the study team to ensure the orderly cessation of study activities to ensure the continuing safety of all study subjects, the study suspension, and may take other action deemed necessary to protect others against unanticipated risks. The IRB may permit study data collected to the point of a subject’s withdrawal to be retained.

3. How should I plan for stopping study activities due to FSU or other non-FSU study site closure related to COVID-19?

**ANSWER:** If delay, postponement or cessation of study activities due to FSU or other study site closure may present risk of harm to any subject’s health and safety (e.g., cessation of study-related clinical treatment previously scheduled), the study team must promptly notify by widest possible dissemination all previously-enrolled subjects, and make arrangements to ensure necessary clinical care of these study subjects outside of the study, such as continued availability of study drugs or clinical follow-up. If however delay, postponement or cessation of study activities will have no adverse impact to study subjects, these subjects must as soon as practicable be informed accordingly, and informed that the study team will follow up with subjects at a later date in order to
reschedule or resume study activities or provide subjects with the opportunity to withdraw from the study. Researchers must promptly notify the IRB if delay, postponement or cessation of study activities may present risk of harm to any subject’s health and safety (e.g., abrupt cessation of study-related clinical treatment). If delay, postponement or cessation of study activities presented no risk of harm to any subject’s health and safety, researchers must notify the IRB before resuming any study interactions or interventions involving study subjects if the delay, postponement or cessation of study activities will require any modification to these study interactions or interventions. The IRB will review the steps taken by the study team to ensure the orderly cessation of study activities to ensure the safety of all study subjects, and may take other action deemed necessary to protect others against unanticipated risks.

4. **My colleagues or I would like to conduct research related to COVID-19; what are the FSU IRB review requirements?**

**ANSWER:** All proposed COVID-19-related research involving human subjects must be submitted to the FSU Office for Human Subjects Protection (OHSP) to determine what federal regulatory and FSU policy human subjects protection review requirements will apply. However, research involving only de-identified COVID-19 information or biospecimens will generally be deemed not human subjects research and therefore not require IRB review; if researchers have any questions or require a related formal determination for such research, refer to the HRP-310 Worksheet for guidance, accessible in RAMP IRB and located as follows: in the IRB tab, the Library tab, Worksheets tab. Also, complete and submit through RAMP IRB the form titled “Determination of Human Subjects Research” available here under Worksheets & Other Documents as an “Official Request for Determination of Not Human Research: https://www.research.fsu.edu/research-offices/ohsp/investigator-resources/templates-and-required-forms/. Otherwise, for any proposed research involving identifiable COVID-19 information or biospecimens or that involves interaction or intervention involving study subjects, FSU IRB review is required; submit proposed research through RAMP IRB, available here: https://myramp.research.fsu.edu/. OHSP and the FSU IRB will as feasible and in accordance with applicable federal regulations, state law and FSU policy try to ensure fast-tracking IRB review of such proposed research.