

*****REVISED*****

INSTITUTIONAL REVIEW BOARD (IRB)-RELATED
COVID-19/CORONAVIRUS DISEASE AND CORONAVIRUS
FREQUENTLY ASKED QUESTIONS (FAQS)
(Version: 5 June 2020)

BELOW IS A LIST OF IRB-RELATED COVID-19/CORONAVIRUS DISEASE FAQS. THE LIST MAY BE UPDATED WITH ADDITIONAL FAQS AS THESE QUESTIONS ARISE OR REQUIRE CLARIFICATION.

NOTE THAT NOTWITHSTANDING THE FAQS BELOW THAT EFFECTIVE MARCH 24, 2020 AND UNTIL FURTHER NOTICE THE FSU OFFICE OF RESEARCH ANNOUNCED THAT RESEARCH ACTIVITIES THAT INVOLVE IN-PERSON INTERACTIONS OR INTERVENTIONS WITH HUMAN RESEARCH SUBJECTS MUST IMMEDIATELY CEASE. GO [HERE](#) FOR THE ANNOUNCEMENT OR SEE <https://news.fsu.edu/announcements/covid-19/2020/03/23/temporary-cessation-to-some-fsu-human-subjects-research/>.

NOTE HOWEVER THAT THERE ARE EXCEPTIONS, including new exceptions permitted by updated FSU policy and which new exceptions are effective June 10, 2020. All exceptions do have limitations or conditions. To obtain details and related information and instructions for conducting or continuing studies that involve in-person or face-to-face activities with study subjects, visit the FSU IRB and Office for Human Subjects Protection's COVID-19 web page for further information and details (available [here](#) or at: <https://www.research.fsu.edu/research-offices/ohsp/covid-19-and-human-research-studies/>).

IRB-RELATED COVID-19/CORONAVIRUS DISEASE FAQS:

1. **If one or more of my study subjects is isolated or quarantined for COVID-19/CORONAVIRUS DISEASE or tests positive for COVID-19/CORONAVIRUS DISEASE 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/CORONAVIRUS DISEASE, ALL STUDY ACTIVITIES INVOLVING ANY IN-PERSON INTERACTION OR INTERVENTION WITH OR BETWEEN ALL STUDY SUBJECTS, AND ANY INTERACTION WITH OR BETWEEN ALL STUDY STAFF MUST IMMEDIATELY CEASE in order to protect study subjects, members of the study team and others. All other government- or FSU-mandated precautions or requirements must be implemented. If cessation of study activities may present immediate 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. If there is risk of COVID-19/CORONAVIRUS DISEASE exposure to study subjects or study staff, then arrangements must be made by the study team to ensure referral of study subjects and study staff to COVID-19/CORONAVIRUS DISEASE screening or testing. Researchers must (1) 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/CORONAVIRUS DISEASE subsequent to taking part in study-related interaction or intervention. Researchers must also (2) promptly notify the IRB about any study subject that is isolated or tests positive for COVID-19/CORONAVIRUS DISEASE subsequent to

taking part in any study-related interaction or intervention—log into RAMP IRB and submit a Report of New Information, describing (a) as much as possible about the study subject’s COVID-19/CORONAVIRUS DISEASE status and the steps taken by the study team to obtain authoritative information about possible COVID-19/CORONAVIRUS DISEASE risks to study subjects and study staff; (b) the risk of harm to study subjects and staff due to the study subject’s COVID-19/CORONAVIRUS DISEASE status; (c) the risk of harm to study subjects due to the abrupt cessation of study-related clinical treatment; (d) provide documentation of the notice to previously-enrolled subjects and study staff; (e) provide documentation of arrangements, when applicable, made by the study team to ensure referral of study subjects and study staff to COVID-19/CORONAVIRUS DISEASE screening or testing; and (f) provide an unequivocal statement to the effect that all study activities involving any in-person interaction or intervention with or between study subjects and any interaction with or between study staff have immediately ceased. 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 based upon the information provided or other information take other action deemed necessary to protect others against unanticipated risks. The IRB may permit study data collected to the point of any subject’s withdrawal to be retained.

IF THE SUBJECT IS QUARANTINED FOR OR IS OTHERWISE REASONABLY BELIEVED TO HAVE BEEN EXPOSED TO COVID-19/CORONAVIRUS DISEASE BUT ARE NOT YET SYMPTOMATIC, ALL STUDY ACTIVITIES INVOLVING THE RELEVANT SUBJECT MUST IMMEDIATELY CEASE; ALL OTHER STUDY ACTIVITIES MUST BE CAREFULLY EVALUATED TO MINIMIZE RISKS TO OTHER STUDY SUBJECTS AND STUDY STAFF, TO INCLUDE CONSIDERATION OF CEASING ANY INTERACTION OR INTERVENTION WITH OR BETWEEN OTHER STUDY SUBJECTS, AND ANY INTERACTION WITH OR BETWEEN STUDY STAFF. Furthermore, all other government- or FSU-mandated precautions or requirements must be implemented. 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/CORONAVIRUS DISEASE risks to subjects and staff is obtained. If cessation of study activities may present immediate 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. If there is risk of COVID-19/CORONAVIRUS DISEASE exposure to study subjects or study staff, then arrangements must be made by the study team to ensure referral of study subjects and study staff to COVID-19/CORONAVIRUS DISEASE screening or testing. Researchers must (1) 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/CORONAVIRUS DISEASE subsequent to taking part in study-related interaction or intervention. Researchers must also (2) promptly notify the IRB about any study subject that is quarantined for or is otherwise reasonably believed to have been exposed to COVID-19/CORONAVIRUS DISEASE subsequent to taking part in any study-related interaction or intervention—log into RAMP IRB and submit a Report of New Information, describing (a) as much as possible about the study subject’s COVID-19/CORONAVIRUS DISEASE status and the steps taken by the study team to obtain authoritative information about possible COVID-19/CORONAVIRUS DISEASE risks to study subjects and study staff; (b) the risk of harm to study subjects and staff due to the study subject’s COVID-19/CORONAVIRUS DISEASE status; (c) the risk of harm to study subjects due to the abrupt cessation of study-related clinical treatment; (d) provide documentation of the notice to previously-enrolled subjects, study sites and study staff; (e) provide documentation of arrangements, when applicable, made by the study team to ensure referral of study subjects and study staff to COVID-19/CORONAVIRUS DISEASE screening or testing; and (f) provide an unequivocal

statement to the effect that all study activities involving any interaction or intervention with or between study subjects and any interaction with or between study staff have immediately ceased, or alternatively provide a rationale for not ceasing study activities. The IRB will review the steps taken by the study team to ensure the continuing safety of all study subjects and study staff, and may based upon the information provided or other information take other action deemed necessary to protect others against unanticipated risks. The IRB may permit study data collected to the point of any 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/CORONAVIRUS DISEASE, tests positive for COVID-19/CORONAVIRUS DISEASE, or has otherwise been exposed to COVID-19/CORONAVIRUS DISEASE 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 immediate 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. If there is risk of COVID-19/CORONAVIRUS DISEASE exposure to study subjects or study staff, then arrangement must be made by the study team to ensure referral to COVID-19/CORONAVIRUS DISEASE screening or testing. Researchers must (1) 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/CORONAVIRUS DISEASE, tested positive for COVID-19/CORONAVIRUS DISEASE, or has otherwise been exposed to COVID-19/CORONAVIRUS DISEASE 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. Researchers must also (2) promptly notify the IRB that one or more study staff has been isolated or quarantined for COVID-19/CORONAVIRUS DISEASE, tested positive for COVID-19/CORONAVIRUS DISEASE, or has otherwise been exposed to COVID-19/CORONAVIRUS DISEASE 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—log into RAMP IRB and submit a Report of New Information, describing (a) as much as possible about the study team member's COVID-19/CORONAVIRUS DISEASE status and the steps taken by the study team to obtain authoritative information about possible COVID-19/CORONAVIRUS DISEASE risks to study subjects and study staff; (b) the risk of harm to study subjects and staff due to the study team member's COVID-19/CORONAVIRUS DISEASE status; (c) the risk of harm to study subjects due to the abrupt cessation of study-related clinical treatment; (d) provide documentation of the notice to previously-enrolled subjects, study sites and study staff; (e) provide documentation of arrangements, when applicable, made by the study team to ensure referral of study subjects and study staff to COVID-19/CORONAVIRUS DISEASE screening or testing; and (f) provide an unequivocal statement to the effect that all study activities involving any interaction or intervention with or between study subjects and any interaction with or between study staff have immediately ceased. The IRB will review the steps taken by the study team to ensure the continuing safety of all study subjects and study staff, and may based upon the information provided or other information take other action deemed necessary to protect others against unanticipated risks. The IRB may permit study data collected to the point of any subject's withdrawal to be retained.

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

ANSWER: All enrolled subjects must as soon as practicable be informed of the cessation of in-person interactions and interventions, 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. There is no need to submit a Modification to the IRB to obtain approval for providing this notice to enrolled subjects, but maintain a templated copy of the notification. However, if the study team plans to substitute virtual or remote study activities for in-person activities involving study subjects, submit a Modification to the IRB for advance review and approval—log into RAMP IRB and submit a Modification, explaining the need for changes to the study on account of stopping in-person study activities due to COVID-19/CORONAVIRUS DISEASE. The IRB will review the proposed modification, and may based upon the information provided or other information take other action deemed necessary to protect others against unanticipated risks.

If delay, postponement or cessation of study activities due to FSU or other study site closure may present immediate risk to a 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. Researchers must also promptly notify* the IRB if delay, postponement or cessation of study activities may present risk of harm to any subject's health and safety—to notify the IRB, log into RAMP IRB and submit a Report of New Information, indicating the risk of harm to study subjects due to the abrupt cessation of study-related clinical treatment, and other risks of harm to study subjects due to stopping the study. The IRB will review the steps taken by the study team to ensure any necessary continuation of clinical care, the COVID-19/CORONAVIRUS DISEASE- and Coronavirus-related precautions taken by the study team, as well as the orderly delay, postponement or cessation of other study activities to ensure the safety of all study subjects. The IRB may based upon the information provided or other information take other action deemed necessary to protect others against unanticipated risks.

*If there is an apparent immediate hazard to study subjects' health and safety, continuing in-person interactions or interventions with study subjects before IRB approval may be authorized; contact the IRB by e-mail (humansubjects@fsu.edu) or telephone (850-644-7900) and provide notice of the continuing interactions or interventions. As soon as practicable log into RAMP IRB and submit a Report of New Information as instructed above.

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

ANSWER: All proposed COVID-19/CORONAVIRUS DISEASE-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. Except as indicated below, research involving only de-identified COVID-19/CORONAVIRUS DISEASE information or biospecimens AND no in-person interaction or intervention with human subjects 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/CORONAVIRUS DISEASE information or biospecimens or that involves COVID-19/CORONAVIRUS DISEASE-related in-person interaction or intervention involving study subjects, FSU IRB review and approval 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.

5. I want to or have taken steps to postpone all study activities due to COVID-19/CORONAVIRUS DISEASE; what do I need to do?

ANSWER: All enrolled subjects must as soon as practicable be informed of the cessation of study-related interactions and interventions, 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. There is no need to submit a Modification to the IRB to obtain approval for providing this notice to enrolled subjects, but maintain a templated copy of the notification.

6. To implement effective social distancing practices I would like to substitute virtual or remote study activities for in-person activities involving study subjects and/or staff; do I need to obtain IRB approval?

ANSWER: YES; BEFORE* RESEARCHERS MAY MODIFY ANY ACTIVITY IN A CURRENT IRB-APPROVED STUDY, A RESEARCHER MUST SUBMIT THE CHANGES TO THE IRB FOR REVIEW AND APPROVAL—log into RAMP IRB and submit a Modification, explaining the need for changes to the study. The changes will generally be reviewed by the IRB through an expedited process. The IRB may based upon the information provided or other information take other action deemed necessary to protect others against unanticipated risks.

*If there is an apparent immediate hazard to study subjects’ health and safety, substituting virtual or remote study activities for in-person activities before IRB approval may be authorized; contact the IRB by e-mail (humansubjects@fsu.edu) or telephone (850-644-7900) and provide notice of the planned changed. As soon as practicable after implementing such a change, log into RAMP IRB and submit a Report of New Information AND a Modification; cross-reference the submissions for ease of IRB handling.

7. My colleagues or I would like submit a new study or modification involving in-person interactions or interventions with study subjects; are there any restrictions or limitations?

ANSWER: YES. As indicated above, although effective March 23, 2020 and pursuant to FSU policy no study involving in-person or face-to-face interaction or intervention with study subjects was permitted to continue or commence, exceptions do apply, including new exceptions permitted effective June 10, 2020. These exceptions do have limitations or conditions. To learn more about

these exceptions and limitations and what may be required to continue or commence studies that involve in-person or face-to-face activities with study subjects, visit the FSU Office for Human Subjects Protection's COVID-19 web page for further information and details (available [here](#) or at: <https://www.research.fsu.edu/research-offices/ohsp/covid-19-and-human-research-studies/>).

8. An external IRB reviewed and approved of my FSU study or study activities; are these studies and study activities subject to the FSU's temporary cessation of in person interactions and interventions with human research participants?

ANSWER: YES. Check with the external IRB to see if the study cessation must be reported, if study subjects must be notified, or if related modifications require the IRB's approval. Each external IRB may have different policies and procedures.

9. What effect does FSU's temporary cessation of studies or study activities involving in-person interactions or interventions have on the review of new, pending or currently-approved studies?

ANSWER: All new, pending and currently-approved studies are subject to FSU's temporary cessation of studies or study activities involving in-person interactions or interventions with human subjects. New and pending applications and modifications to currently-approved studies are prioritized as follows: all new applications and modifications that involve COVID-19 or Coronavirus Disease, or their impact upon on-going studies; new applications and modifications that are permitted as exceptions to the temporary cessation; and all other new applications or modifications (review of these studies may be delayed so plan accordingly).

10. Will the IRB accept and review applications for new studies or modifications for existing studies that will involve in-person interactions or interventions with human research participants that will take place AFTER the restrictions on these activities is lifted?

ANSWER: YES. Although in-person activities involving human research participants may not, unless there is an exception, take place or resume until the cessation of such activities is lifted, the IRB will accept and continue to review applications for new studies or modifications for existing studies that will involve in-person activities involving human research participants. Study activities that do not involve in-person interactions or interventions with human research participants (e.g., online recruitment; collection of data through web-based surveys; telephone screening of prospective human research participants; virtual focus groups) may if approved by the IRB commence. While the cessation is in effect, IRB approvals of in-person activities involving human research participants will, if not an exception, be conditioned upon not conducting these in-person activities until such time as the cessation is lifted. Moreover, the study team need not submit to the IRB a modification to request only approval to commence in-person activities if those in-person activities have already received IRB approval.

FOR COVID-19/CORONAVIRUS DISEASE-RELATED FEDERAL GUIDANCE FOR RESEARCHERS, GO [HERE](#) OR <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-087.html>