

SOP: Study-Specific COVID-19 Risk Mitigation Planning

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1 PURPOSE

- 1.1 This SOP describes the process for:
 - 1.1.1 Determining whether study-specific risk mitigation plans are needed to address additional research subject safety considerations associated with the COVID-19 pandemic;
 - 1.1.2 Developing study-specific COVID-19 risk mitigation plans;
 - 1.1.3 Communicating study modifications to the IRB; and
 - 1.1.4 Documenting any implemented modifications or deviations from the protocol in the research record.
- 1.2 The process begins when the investigator considers whether a study-specific risk-mitigation plan is necessary during the COVID-19 pandemic.
- 1.3 The process ends when the investigator develops the risk mitigation plan or determines that no plan is necessary.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 On March 24, 2020 FSU announced the immediate temporary cessation until further notice of research activities that that involve in-person interactions and interventions with human research participants. The FSU announcement was updated June 5, 2020. The cessation was imposed in order to minimize COVID-19 and Coronavirus Disease risks to human research participants and to the community.
 - 3.1.1 This temporary cessation applies to all on-going studies or study procedures (including exempt studies or study procedures) that involve in-person interactions or interventions with human research participants except those that involve:
 - 3.1.1.1 Studies involving in-person interactions or interventions that comprise or that can be modified to appropriate remote interactions (e.g., web-based, telephone calls, emails) and which interactions and interventions don't compromise human subject safety;
 - 3.1.1.2 A substantial likelihood of direct and meaningful biomedical or behavioral health-related benefit or outcome for individual human research participants;
 - 3.1.1.2.1 Substantial likelihood of direct and meaningful biomedical or behavioral health-related benefit or outcome means that participation in the study has a good probability of directly having a meaningful positive impact on the serious medical or serious psychological condition of individual subjects for one or more of the study groups;
 - 3.1.1.2.2 Examples include:
 - 3.1.1.2.2.1 Mitigation or cure of a serious disease;
 - 3.1.1.2.2.2 Significant reduction of serious disease burden;

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3.1.1.2.2.3 Treatment or stabilization of a serious medical or psychological condition that is having a significant negative impact on the human research participants;

3.1.1.2.2.4 Diagnosis of a serious condition that is treatable and that would otherwise not be known to the human research participant; and,

3.1.1.2.2.5 Pharmacologic or non-pharmacologic self-management for diabetes or cancer symptoms;

3.1.1.3 Clinical trials where all in-person interactions and interventions occur only within the context of a necessary clinical care visit and for which continuing interactions and interventions take place only at a licensed health care facility or medical practice office; clinical trial-related activities (such as for example screening, follow-up or safety monitoring) that can be done remotely must be done that way; or,

3.1.1.4 Diagnosis, treatment, interventions, or other research activities directly focused on COVID-19 or Coronavirus Disease.

3.1.1.5 Studies involving in-person interactions and interventions that conform to required conditions for social distancing, COVID-19 risk mitigation, use of related protocol and consent templates, and exclusion of persons deemed at higher risk for severe illness from COVID-19. Refer to our HRP-502COVID-Protocol- and Consent-related COVID Template and Instructions document [here](#) or access the document in [RAMP IRB](#) under the IRB, Library and Templates tabs.

3.1.2 New studies or study procedures that involve in-person interactions or interventions with human research participants will only be accepted for FSU Institutional Review Board review if the studies meet the above conditions.

3.2 Any other exception must be discussed with the Director, FSU Office for Human Subjects Protection. Any study or study procedure granted an exception is still subject to IRB review and approval.

4 RESPONSIBILITIES

4.1 Investigators are responsible to carry out these procedures.

5 PROCEDURE

5.1 Determine whether a COVID-19 risk mitigation plan should be developed for each Human Research project the investigator is leading.

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- 5.1.1 A COVID-19 risk mitigation plan should be developed for all studies for which an exception applies unless one of the following is true:
 - 5.1.1.1 Research does not any involve in-person interaction or intervention with human research participants.
 - 5.1.1.2 Research is externally sponsored, and Sponsor has already developed a COVID-19 risk mitigation plan for the research. If an external sponsor has developed a COVID-19 risk mitigation plan for the research, skip to step 5.4.

- 5.1.2 A risk mitigation plan must include, based upon the likelihood of direct and meaningful biomedical or behavioral health-related benefit or outcome for individual human research participants, the following, as applicable:
 - 5.1.2.1 For research that *does not* offer substantial likelihood of direct and meaningful biomedical or behavioral health-related benefit or outcome for individual human research participants (including Phase I trials for which treatment alternative exists):
 - 5.1.2.1.1 All in-person interactions and interventions that can be done remotely must be done that way; in-person interactions and interventions involving human research participants that cannot be done remotely should be put on hold.
 - 5.1.2.1.2 For in-person interactions and interventions involving human research participants that cannot be placed on hold, develop a plan to conduct in-person interactions and interventions only within the context of a necessary clinical care visit and for which continuing interactions and interventions take place only at a licensed health care facility or medical practice office. Go to this U.S. government link for COVID-19 to search for and obtain relevant information: <https://www.coronavirus.gov/>.
 - 5.1.2.1.3 For all other in-person interactions and interventions involving human research participants, the mitigation plan must include relevant and applicable COVID-19 and Coronavirus Disease safety protocols and precautions established for interaction or interventions involving individuals. Go to this U.S. government link to search for and obtain relevant COVID-19 information: <https://www.coronavirus.gov/>.
 - 5.1.2.2 For research that *does* offer substantial likelihood of direct and meaningful biomedical or behavioral health-related benefit or outcome for individual human research participants (or is a Phase I trial with no treatment alternatives):

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- 5.1.2.2.1 Determine whether the study or study procedures involving in-person interactions and interventions involving human research participants should be placed on hold; or,
- 5.1.2.2.2 Develop more detailed risk mitigation plan, considering the items included in WORKSHEET: Protocol-Specific COVID-19 Risk Mitigation Planning (which is based upon the FDA’s “Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic”). In addition, go to this U.S. government link to search for and obtain relevant COVID-19 information: <https://www.coronavirus.gov/>.

5.2 Submit a Modification in RAMP IRB if the risk mitigation plan involves revising study procedures or if otherwise instructed:

5.2.1 If immediate modification of the research is necessary to eliminate an apparent immediate hazard to a human research participant, take action and notify the IRB within 10 business days via RAMP IRB by a Report New Information (RNI) submission.

5.2.2 For all other study modifications made to ensure the ongoing safety of human research participants, submit in RAMP IRB a study modification utilizing the “Create Modification/CR” button on the study workspace, and selecting a modification to “other parts of the study” in the SmartForm. Upload form “HRP-219 - FORM - COVID-19 Modification” in the “Other Attachments” section of the “Local Site Documents” page of the study SmartForm.

5.3 Document mitigation plan details in study record in accordance with sponsor and regulatory agency requirements, and in accordance with the information listed in “HRP-350 - WORKSHEET - Research-Specific COVID-19 Risk Mitigation Plan.”

6 MATERIALS

- 6.1 HRP-219 - FORM - COVID-19 Modification
- 6.2 HRP-350 - WORKSHEET - Research-Specific COVID-19 Risk Mitigation Plan

7 REFERENCES

- 7.1 [FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic](#)