1 PURPOSE

1.1 This standard operating procedure (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.

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 Until the COVID-19 pandemic is more effectively contained and managed, investigators should temporarily place recruitment and ongoing research procedures on voluntary hold for human research that requires *direct contact* with research subjects but *does not offer direct benefit* to participants (with the exception of a Phase I trial with no treatment alternatives).

4 RESPONSIBILITIES

4.1 Investigators are responsible for carrying 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. A COVID-19 risk mitigation plan should be developed unless one of the following is true:

5.1.1 Research does not involve in-person interaction with research subjects.

5.1.2 Research can be conducted as written while adhering to social distancing[1] requirements and institutional COVID-19 policies and requirements.

5.1.3 Research is externally sponsored, and the sponsor has already developed a COVID-19 risk mitigation plan for the research.

5.1.4 Research has been voluntarily placed on hold for recruitment, and all research procedures (with the exception of necessary follow-up procedures to be done consistently with social distancing requirements and institutional COVID-19 policies and requirements).

5.2 If an external sponsor has developed a COVID-19 risk mitigation plan for the research, skip to step 5.4.

[1] Social distancing recommendations include the following: that people stay at home as much as possible, going out only for critical needs like groceries and medicines, or to exercise and enjoy the outdoors in wide-open spaces. Other recommendations include avoiding gatherings of more than 10 people, no handshakes, regular handwashing and, when encountering someone outside of your immediate household, trying to remain at least 6 feet apart. (Source: NIH Director's Blog, March 19, 2020)

5.3 For all other research involving in-person interactions with research subjects for which the research cannot otherwise be conducted in accordance with social distancing recommendations, develop a risk mitigation plan in consideration of the potential for direct therapeutic benefit associated with the research.

5.3.1 For research that *does not* offer potential for direct therapeutic benefit (and is not a Phase I trial with no treatment alternatives):

5.3.1.1 Develop a plan to place study recruitment and study activities on voluntary hold.

5.3.1.2 Notify the IRB if study recruitment and research activities cannot be placed on hold for any research requiring in-person interaction but offering no potential for direct therapeutic benefit.

5.3.2 For research that *does* offer potential for direct therapeutic benefit (or Phase I trial with no treatment alternatives):

5.3.2.1 Determine whether the study should be voluntarily placed on hold to recruitment and/or study conduct, or

5.3.2.2 Develop more detailed risk mitigation plan, considering the items included in Worksheet: Protocol-Specific COVID-19 Risk Mitigation Planning, based on the Food and Drug Administration's (FDA) Guidance on Conduct of Clinical Trials of Medical Products During COVID-19 Pandemic.

5.4 Notify the IRB and applicable ancillary review committees (e.g., DSMB, DSMC, etc.) of the risk mitigation plan:

5.4.1 If immediate modification of the research is necessary to eliminate an apparent immediate hazard to a subject, take action and notify the IRB following the standard pathway to submit reportable new information.

5.4.2 For all other study modifications made to ensure the ongoing safety of research subjects during the COVID-19 pandemic, submit a study 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.

5.5 Document mitigation plan details in the 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 Attached Appendix to SOP-092

7.2 FDA Guidance on Conduct of Clinical Trials of Medical Products During COVID-19 Pandemic