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Appendix A-12 **COVID-19 Considerations for Investigators Conducting Human Research**

Investigators conducting Human Research during the COVID-19 pandemic should be aware of the following additional considerations related to their ongoing interactions with the IRB:

Deciding Whether a Study-Specific COVID-19 Risk Mitigation Plan for Ongoing Research is Needed

In general, investigators should develop a study-specific COVID-19 risk mitigation plan for their research unless one of the following is true:

- Research does not any involve in-person interaction or intervention with human research participants.
- Research is externally sponsored, and Sponsor has already developed a COVID-19 risk mitigation plan for the research.

Tools and Resources for Developing Study-Specific COVID-19 Risk Mitigation Plans for Ongoing Research

Review HRP-092: “SOP: Study-Specific COVID-19 Risk Mitigation Plans” and HRP-350: “WORKSHEET: Protocol-Specific COVID-19 Risk Mitigation Planning” for general guidance on developing study-specific risk mitigation plans. For FDA-regulated research, consult [FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic](#) as well for further information.

COVID-19 Screening Procedures: Is an IRB Modification Needed?

COVID-19 screening procedures that are mandated by FSU for clinical trials do not necessarily need to be reported as modification to the protocol, even if done during clinical study visits, unless the sponsor is incorporating the data collected as part of a new research objective. For information about modification requirements, see HRP-092: “SOP: Study-Specific COVID-19 Risk Mitigation Plans.”

Voluntary Holds on Human Research Activities

Investigators may voluntarily elect to place all recruitment, enrollment, and research procedures on temporary hold if doing so will better ensure the safety of research subjects and would not create any additional risks to the safety and welfare of research subjects. Such voluntary holds on research activity and resumption of previously-IRB approved activities do not require IRB notification or review.

Submitting Study-Specific COVID-19 Risk Mitigation Plans for IRB Review

If immediate modification of the research is necessary to eliminate an apparent immediate hazard to a subject, take action and notify IRB following the standard pathway to submit Reportable New Information.

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For all other study modifications made to ensure the ongoing safety of research subjects during the COVID-19 pandemic, submit a study amendment and all relevant new or modified study materials to the IRB using HRP-219: “FORM: MODIFICATION DUE TO COVID-19.”

Other Reportable New Information Considerations During the COVID-19 Pandemic

This institution’s list of reportable events includes two items for which additional clarification and guidance may be helpful during this time.

Item #8f on this institution’s list of reportable events (in the Investigator Manual) states (emphasis added) “Failure to follow the protocol due to the *action or inaction of the investigator or research staff.*” Emphasis on action or inaction of the investigator or research staff has been added because this requirement does not include action or inaction of the research subject. For example, study teams may notice an increase in the number of subjects who do not arrive for scheduled research visits. Failure of a research participant to appear for a scheduled research visit is not noncompliance due to action or inaction by the investigator or research staff, and therefore does not require reporting to the IRB.

Item #8h on this institution’s list of reportable events states “Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.” It is recognized that during this pandemic there will be cases where there is sufficient time to receive IRB approval of any proposed modifications to previously-approved research, and in such cases, investigators should follow standard IRB procedures for submitting modifications. However, there will be other cases where investigators must make more immediate changes to the protocol or investigational plan to minimize or eliminate immediate hazards or to protect the life and well-being of research participants (e.g., to limit exposure to COVID-19). Such changes may be implemented without IRB approval, but are required to be reported to the IRB in accordance with IRB policies and procedures for submitting Reportable New Information.

Expanded Access Requests

Expanded access is a potential pathway for a patient with an immediately life-threatening condition or serious disease or condition to gain access to an investigational product for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available. The FDA does not consider Expanded Access to be “research” but does require IRB review and approval before treatment may begin (except for emergency access use when there is not sufficient time to secure prospective IRB review).

A licensed physician must submit Expanded Access Requests to the FDA as a protocol under a new IND. There are three request types:

- Non-Emergency Individual Patient IND (submitted prospectively)
- Emergency Use Individual Patient IND (submitted retrospectively)
- Intermediate-size Population IND (submitted prospectively)

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See the FDA website for guidance and instruction for how to submit the appropriate IND to the FDA (<https://www.fda.gov/news-events/expanded-access/expanded-access-how-submit-request-forms>).

IMPORTANT: When completing FDA Form 3926 be sure to select box 10b to “Request Authorization to Use Alternate IRB Review Procedures” so the IRB can expedite the review of the Expanded Access Request.

Once complete, contact the IRB Office immediately to discuss the request, and ask for HRP-506-TEMPLATE CONSENT DOCUMENT - Emergency or Compassionate Device Use so that you may prepare your consent document. Using the “Report New Information” activity, submit the treatment protocol reviewed by the FDA, the consent form, the eIND and completed FDA Form 3926.