

Effective immediately, the University will use the following guidelines when assessing whether specific human subject research projects may continue at UF. These guidelines are for human subject research only, pertinent only during the current COVID-19 epidemic, and will be in place until removed by the UF Vice President for Research. Since this crisis is fluid, these recommendations may change over time:

| Tier | Potential <u>Health Benefit</u> to Participants | Activities | Enrollment | Alternatives |
|------|--|--|---------------|--|
| 1 | COVID-19 research | Activities may continue. | May continue | NA |
| 2 | Direct <u>health benefit</u> , serious risk to subjects if study interventions stopped | Activities may continue. | Paused/halted | May request exception to enroll new subjects, see below. |
| 3 | Low to no direct <u>health benefit</u> , no face to face interactions with study subjects or between study staff. | Activities may continue, however any on-campus research activities must have prior approval by your appropriate Dean and UF Vice President for Research (VPR). | May continue | NA |
| 4 | Low to no direct <u>health benefit</u> , with face to face interactions with study subjects or between study staff. | All activities that involve face to face interaction with subjects or between study staff must be halted.* | Paused/halted | * See COVID-19 Investigator Guideline |

Based on the above table:

Tier 1 – COVID-19 Research

Activities may continue. As part of the submission, you must describe safeguards you are taking to protect human subjects and researchers engaged in research that may come into contact with known or unknown infected individuals or materials in the conduct of the research.

Tier 2 – Direct Health Benefit to Research Participants

All protocols in which serious or immediate harm could be caused to the research participants if research activities are stopped.

For example:

- Research protocols involving treatments for acute, life threatening health conditions (e.g. some treatment trials for cancers)
- Protocols where stopping the intervention (e.g., some investigational drugs or vaccines or preventative drug regimens) could be harmful to the subjects

For FDA governed clinical trials, please refer to the FDA guidance at

<https://www.fda.gov/media/136238/download>

Research in Tier 2 can continue if the PI ensures the research can be conducted in a safe manner that protects subjects, researchers and staff, and the community.

Enrollment of new subjects must be paused unless there is a compelling reason to enroll new subjects.

- Compelling reasons include:
 - There is a potential life or limb savings for the new study subject if enrollment is delayed over the next 2 months.
 - The study interventions cannot be obtained outside of the approved research protocol
 - Any direct contact by research personnel with study subjects must follow CDC and any state and UF COVID 19 guidelines
- If study personnel must come on campus for research purposes only the PI must obtain approval from their dean or department chair.
- Compliance with this guideline is the responsibility of the Principal Investigator. Violations of this guideline will be considered serious protocol violations that would be reported the FDA or OHRP per UF policy.
- Should the PI determine that there is a compelling reason to allow his or her protocol to continue study enrollment, the PI must document in their study records how they justified that decision.
- If you are unsure and would like the IRB to make the decision, please submit a miscellaneous reportable event submission within myIRB. You must complete and upload this request form : <http://irb.ufl.edu/wp-content/uploads/tier2exception.docx>.

Tier 3 – Low to No Direct Health Benefit to Research Participants

Research that has **no** face to face interaction or intervention with subjects.

- Chart review studies
- Research interactions conducted online or over the phone
- Analysis of previously collected data/tissue

Research activities in Tier 3 may continue conducting all activities and enrolling subjects provided there is never any face to face interaction with subjects. If this involves on-campus activities, this will also require prior review and approval by the appropriate Dean and the UF VPR.

Tier 4 – Low to no Direct Health Benefit to Research Participants

Research in these categories that include face to face interaction with subjects.

- Cohort and natural history studies where delays in data collection have limited impact on scientific objectives
- Protocols in which delays to starting or pausing of research does not substantively impact on research objectives of the research protocol
- Protocols in which risks to research participants are higher (e.g., potentially exposing elderly vulnerable individuals to COVID) and benefits of the study to the participants remain minimal
- Research with healthy volunteers
- Any minimal risk studies that require research subjects to travel, that involve students, or that are in a community setting and require direct interaction with researchers

*Research activities in Tier 4 must **not** enroll new participants in studies requiring face to face interaction **nor** continue to conduct face to face visits. Activities that do not require participant interaction may continue. Researchers may also submit a revision to the IRB to conduct interactions online or via phone.*

Items to consider:

- **OTHER RESTRICTIONS:** UF Health, CTSI, UF Cancer Center, and/or other units may set or change restrictions that impact human research. It is imperative that researchers comply with all applicable restrictions/requirements as we respond to the COVID-19 pandemic. Please see the UF Health Updates page <http://www.ufl.edu/health-updates/>.
- **Reduce Study Visits:** To the extent reasonable and appropriate, researchers should propose to replace in-person study visits with virtual study visits, using phone, email, and internet- based video technology. Please refer to the UF IRB Investigator Guideline <http://irb.ufl.edu/wp-content/uploads/Temporary-Guideline-COVID-19-Related-Protocol-Revisions.pdf> or contact the UF IRB promptly for guidance on submitting protocol amendments to address proposed changes to study procedures. *If you are uncertain about whether a change requires IRB approval prior to implementation, please contact the IRB office immediately.*
- **Research Contracting Issues:** Should your study be placed on hold by UF, you may need to consult with an appropriate funding agency. If you have questions, please contact the following:
 - **Contractual issues:** Brian Sevier bjse@ufl.edu.
 - **Federally funded issues:** Stephanie Gray slgray@ufl.edu.
- **Consult Travel Advisory:** Given the University’s restrictions on international and essential-only domestic travel, researchers should consult the UF COVID-19 website (<http://www.ufl.edu/health-updates/>) for up to date information. Please also refer to the CDC page on their link under travel information <https://www.cdc.gov/coronavirus/2019-ncov/travelers/index.html>

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- **Develop a Script for Participants:** Research teams should consider developing a script outlining for research participants how UF is making the environment as safe as possible when they come in for their research visit. Please make sure to determine if the study subject wants to remain in the study, and if not, what their options are.
- **Multi-site studies where UF is serving as the sIRB for other institutions:** the restrictions of this guidance must be communicated to all of the relying site investigators by the overall lead PI of the study. Relying site investigators must also ascertain if their institution has implemented more restrictive requirements. Relying site investigators need to comply with whatever requirements are most restrictive and communicate same to the lead PI.
- **sIRB Studies ceded to another IRB:** If oversight for your study is ceded to an external IRB, communicate UF’s guidance to the overall lead PI and the reviewing IRB, especially if your research is placed on hold by UF, per the tier system spelled out above.

Develop Contingency Plans:

Study teams should immediately prepare contingency plans for their active research protocols. **These changes may require IRB approval prior to implementation** (see: <http://irb.ufl.edu/wp-content/uploads/Temporary-Guideline-COVID-19-Related-Protocol-Revisions.pdf>). Consider whether disruption of a research protocol will impact the safety of your research participants, and how you can manage that disruption:

- **Investigational Drugs** – If you have specific questions related to investigational drugs, at UFHealth Gainesville, please contact the Investigational Drug Service at IDS@shands.ufl.edu or call 352-294-5894. Currently the IDS is open regular business hours Monday to Friday 7:30am to 4:00pm at both locations, Shands North Tower and CTSI. For UFHealth Jacksonville, on the Jacksonville or North campuses, please contact the Clinical Research Service (CRS) at researchpharmacist@jax.ufl.edu or page 904- 393-4191. Currently CRS is open regular business hours Monday to Friday 8 am to 4:30pm. If research participants are on investigational drugs, work with the IDS to determine what the plan would be if the investigational drug could not be dispensed to your research participants. You might find a way to deliver investigational drugs to their home. If the investigational drugs cannot be dispensed to our research participants, you should make plans to transition research participants back onto their most appropriate clinically available medications. This transition should include consultations with the investigation drug service and the clinical team caring for the research participants. Where the investigational drug is administered under an external, sponsor-held IND, the sponsor should be proposing any protocol changes needed to the FDA protocol and IRB protocol to the FDA and responsible IRB.
- **Consider Pausing Study Procedures:** For studies where appropriate, individual investigators may choose to temporarily pause enrollment. PIs need to assess whether any reduction in staff makes it unsafe to complete the planned research procedures. Even routine research interventions might not be easy or safe if experienced staff are not available.
- **Timely review of research data** – If research team members are not available, integration of research care such as reviewing lab results in a timely manner might not be possible and will

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require special attention under the direction of the study PI. Study teams should consider the availability of appropriate back-ups to the PI to make safety assessments.

- **Utilization of alternate visit options:** including telephone or Zoom visits for participants who are unable or unwilling to come to on-site visits. Remember, you must use IT Security approved methods.
- **Home visits:** Some essential research visits may require blood draws or simple measurements like BP and BMI assessments that could be accomplished with a home visit. Before moving to home visits, research teams need to consider: can the activity be done safely in the home, as PI do you acknowledge that the research staff doing the home visits have been appropriately trained, does the research staff member have any health conditions or current symptoms related to the coronavirus, and does the research participant or other individuals in the home have symptoms that would indicate a high risk of coronavirus transmission. Up to date screening questions should be utilized to make the assessment about risk of coronavirus transmission. Research teams should follow the current policy that two members of the research team be present for home visits.
- **For investigators with Epic access:** The research visit must be documented in Epic and include the following information: did the research participant pass the screening questions about risk for infection, what times did the research team enter and leave the house, and who else was present in the home during the visit.