COVID-19 Investigator Guideline

Modified: March 27, 2020

Background:

Due to the unprecedented COVID-19 emergency, investigators may be required to alter their protocols in ways to minimize the spread of this virus. The following outlines when or if the IRB needs to be notified. If you have any questions, please email irb@ufl.edu.

1) Q: Should I continue my protocol under the COVID-19 emergency?

All human subjects researcher are required to follow the guideline on conducting human research issued by Dr. Norton, Vice President for Research at UF https://research.ufl.edu/wp-content/uploads/humanresearchcovid.pdf

2) Q: What types of changes can I make to my protocol that do not require IRB approval?

In general, changes that:

a) Are temporary in nature in order to limit subject exposure to the virus. This means that when this crisis is over, you will return to all pre-crisis procedures
   i) Examples:
      (1) Delaying return visits or other study related interventions
      (2) Conducting follow-up information or data collection over the phone or similar devices.
         (a) Remember, If the change involves interactions over the phone or some other similar device, or collecting information-electronically, you must use products approved by IT Security. Fast path solutions include UF Zoom or UF Zoom HIPAA and REDCap. Please refer to the IT Security website https://it.ufl.edu/policies/information-security/.
         (b) Please remember that this is particularly important when collecting sensitive information.
   b) Do not add any additional risk to any subjects or study staff
   c) You should make a note to file in your study records of what minor temporary change(s) were made along with the justification in case you are ever audited.

3) Q: What type of changes “must” be approved by the IRB prior to implementing them?

In general, changes that:

a) Any change in the method for obtaining informed consent
b) Are not being made as a direct result of the COVID-19 crisis no matter how minor (see IRB Guideline on Revisions).
c) Are greater-than-minimal risk changes that are a result of the COVID 19 crisis
d) Are permanent changes that will remain once the COVID crisis has resolved.

4) Q: What if the greater-than-minimal risk revision can’t wait for IRB approval?

a) If it is in the best interest of the subject, and will minimize or prevent subject injury, then make the change.
   i) You should call the IRB chairperson when time allows
   ii) You must submit this revision to the IRB as soon as possible, noting that the revision was
implemented emergency, including the justification for that emergent change.

5) **Q:** What if there is a desire or need to keep a temporary COVID-19 related change a permanent change?

   a) If the change is consistent with item #2 above, then initiate the change and submit the revision.
   b) When you submit the revision, please include in the description of the revision that the change was already implemented, and the reason it was implemented “emergently”.

6) **Q:** What if you decide to temporarily stop your study until the COVID-19 crisis is over?

   a) If you are following the UF Research guideline [https://research.ufl.edu/wp-content/uploads/humanresearchcovid.pdf](https://research.ufl.edu/wp-content/uploads/humanresearchcovid.pdf), there is no need to inform the IRB.
   b) If you are temporarily stopping a protocol that is greater-than-minimal risk and involves the potential direct health benefit to subjects, you must submit that revision to the IRB before **stopping your study**.
      i) The exception to this is if stopping the study is necessary to avoid direct subject harm
      ii) You must ensure your hold on your study does not increase any risk to those study subjects.
      iii) Make sure you contact any study subject who will be affected by this temporary closure (eg. a study visit will be cancelled, etc.)
   c) You should make a note to file in your study records of this temporary suspension along with the justification and any actions taken in case you are ever audited.

**Submitting COVID-19 Related Research to the IRB**

7) **What is the process to submit COVID 19 related protocols to the IRB?**

   a) If your study will involve UFHealth hospital or clinic patients, please contact Mark Brantly, M.D. at Mark.Brantly@medicine.ufl.edu. UFHealth has established a committee to review and prioritize COVID 19 related research. Final approval from the IRB will be contingent on receiving communication from this committee that your study has been approved to move forward.
   b) Simultaneously or if your research does not involve UFHealth hospital or clinic patients:
      i) Submit your study within the IRB software, myIRB, as usual
      ii) Email Drs. Iafrate iafrate@ufl.edu and Simic isimic@ufl.edu at the IRB to inform them of your COVID related study, including the IRB number.
      iii) Based on the risk to subjects to participate in the research
         1) If minimal risk, it will be prioritized to an Executive Reviewer
         2) If greater-than-minimal risk, it will be assigned to the next Full Board meeting. IRB-01 is now having weekly meetings; the off weeks are strictly for COVID related research.
   c) In all cases, you must assign a knowledgeable person of the study for the IRB work with to resolve issues. Also, if it is a Full Board protocol, a knowledgeable person of the study must zoom into the appropriate IRB Meeting to answer questions.

8) **Are there special considerations that should be addressed in IRB submissions related to COVID 19 studies?**

   Yes,
   a) Consenting subjects – Please think through the various ways you might have to consent study subjects and include all options you think are appropriate. The consenting options are:
      i) Subject is capacitated
         1) They are given the consent form securely in their room, once you have reviewed the
consent via a phone call into the room, have an uninvolved witness, outside of the room, sign on the consent document, that the subject verbally agreed, or

(2) You can use the clinical app Haiku, to take a picture of the subject signed consent as long as the Haiku apps hospital process is followed.

ii) Subject is incapacitated, then a Legally Authorized Representative (LAR) must be consented
(1) If the LAR is available in person, review the consent, have the LAR sign for the patient
(2) If no LAR is available on site, you will need to call the LAR:
   (a) Ideally email them a copy of the consent and review, record approval with a witness on the phone line and document same in your research records
   (b) If an email can’t be sent, then you need to review the entire consent over the phone, record approval with a witness on the phone line
(3) If no LAR available is available – The only way you could enroll in this case is if it is determined by a physician not involved in this study, determines that being in the study is potentially lifesaving. If that is the case, that uninvolved physician must document this in the patient’s chart along with the reasoning for making that decision.

b) Please review the guideline on conducting human research issued by Dr. Norton, Vice President for Research at UF https://research.ufl.edu/wp-content/uploads/humanresearchcovid.pdf for more issues to consider.

9) What should I do if I have a new application, change in research or protocol event that is related to COVID-19 that may need to be reviewed urgently?

Submit the revision and email Drs. Iafrate iafrate@ufl.edu and Simic isimic@ufl.edu at the IRB to inform them of your COVID related study, including the IRB number.