COVID-19 Related Temporary Protocol Revisions

Modified: March 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

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

   This is an individual investigator decision, unless the University or Shands places additional restrictions. Please take into account any added risk to the subjects, in particular, those subjects that may be at heightened risk from this disease vs the true need to continue your research during this crisis. Please reference the CDC website [https://www.cdc.gov/coronavirus/2019-ncov/index.html](https://www.cdc.gov/coronavirus/2019-ncov/index.html).

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) 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/](https://it.ufl.edu/policies/information-security/).

      ii) 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) Are not being made as a direct result of the COVID-19 crisis no matter how minor (see IRB Guideline on Revisions).

   b) Are greater-than-minimal risk changes that are a result of the COVID 19 crisis

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 suspend your study until the COVID-19 crisis is over?

a) There is no need to inform the IRB. However,
   i) If your study is a greater-than-minimal risk study that involves some type of patient care, you must ensure your suspension does not increase any risk to those study subjects.
   ii) If possible, make sure you contact any study subject who will be affected by this suspension (eg. a study visit will be cancelled, etc.)

b) 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.