**Coronavirus Update: Temporary IRB Protocol Revisions**

*March 13, 2020* -- Because of the unprecedented coronavirus -COVID-19 - situation, investigators may be required to alter their research protocols in some way to minimize the spread of this virus. We know this has IRB implications, so we are providing Temporary Protocol Revisions, procedures and guidance on when to notify the IRB.

**Should I continue my protocol during the COVID-19 period?**

This is an individual investigator decision, unless UCF places additional restrictions. Please consider 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.

**What types of changes can I make to my protocol that do not require IRB approval?**

In general, changes that:

*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.

**Change on interaction methods, such as changes from face-to-face to over the phone or some other similar devices.

**Please remember that this change can only be implemented if it presents no greater risk to participants. For example, if your study was taking place in person to avoid the risk by direct observations of the research subjects, a change to over the phone would not be permitted without a formal review by the IRB in the form of a modification.

** Do not add any additional risk to any subjects or study staff.

**You should make a note in your study records regarding the above mentioned minor temporary change(s) that were made along with the justification in case you are ever audited.

**What type of changes "must" be approved by the IRB prior to implementing them?**

In general, changes that:

* Are not being made as a direct result of the COVID-19 crisis, no matter how minor.
* Are greater-than-minimal risk changes that are a result of the COVID 19 crisis.
* Are on the protocol that is a greater-than-minimal risk study.

**What if the greater-than-minimal risk revision can't wait for IRB approval?**

If it is in the best interest of the subject, and will minimize or prevent transmission of COVID 19, then make the change, however:

* You should immediately notify the IRB by email at IRB@ucf.edu.
* You should make a note the change(s) in your study records with the justification.
* You must submit the revision of protocol with the change(s) to the IRB as soon as possible, noting that the revision was implemented because of an emergency, including the justification for that emergent change(s).

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

*If the change is consistent with item #2 above, then initiate the change and submit the revision.
* 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".

**What if you decide to suspend your study until the COVID-19 crisis is over?**

* There is no need to inform the IRB. However,
  **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.
  **If possible, make sure you contact any study subject who will be affected by this suspension (i.e., a study visit will be cancelled, etc.)
  **You should make a note in your study records of this temporary suspension along with the justification and any actions taken in case you are ever audited.

If you have any additional questions, contact the IRB at IRB@ucf.edu. Please be patient as we anticipate a large volume of requests at this time.