**Changes in Response to COVID-19**

**Change in Research Submission Form**

WCG recognizes that swift changes in research may be necessary in response to the COVID-19 pandemic. This form has been created to provide a pathway to communicate these deviations or other changes in research to the IRB.

**Please note that this form can be used for both Canadian and US studies**

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| --- | --- |
| **IRB Protocol Number**  (*also called IRB Tracking Number*) |  |
| **Sponsor Protocol ID**  *(if applicable)* |  |
| **Protocol Title** |  |

**FOR WHOM ARE YOU SUBMITTING (choose one)**

Sponsor or Contract Research Organization (CRO)

Apply to all investigators

Apply to specific investigators only (listed below)

Site Management Organization

Investigator(s) (listed below)

Site (**Investigator name**:      )

I confirm that the sponsor has been informed of and approved the site’s planned/implemented actions.

Provide documentation of sponsor/CRO acknowledgement.

**SUBMISSION TIMING (choose one)**

Preferably, changes to research should be submitted to the IRB prior to implementation. However, the IRB recognizes that the regulations allow changes to eliminate apparent immediate hazards to subjects to be implemented prior to IRB review (FDA 21 CFR 56.108(a)(4), HHS 45 CFR 46.108(a)(3) and the Canadian regulations TCPS 2 (2018) Article 6.15). These changes must be submitted to the IRB within 5 days after implementation.

**Changes submitted will be implemented after IRB review and approval**

**Changes submitted have already been implemented**

If changes were implemented greater than 5 days ago, you must provide an explanation for the delay in reporting to the IRB either below or submitted in an attachment to this submission.

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**SUBMISSION DOCUMENTS (choose as applicable):**

*All Changes in Research are subject to standard IRB review fees.*

**Letters or directives to subjects**

**Revised Consent Form or Informed Consent Form Addendum**

With which subjects do you plan to use the revised consent form or addendum?

All current subjects and all future subjects

Only future subjects

Other

**Protocol Amendment, Deviation Memo, Administrative Change Memo, Protocol Clarification, Investigator Notice, or other change in research documentation**

**Site Status**

For site actions, provide documentation that the sponsor/CRO has been notified and has acknowledged the site’s actions

Site will suspend all or some study activities during pandemic period with plans to resume when feasible

* + - Choose one:

There are no more active subjects left or the only subject interaction is limited to follow-up calls or questionnaires

There are still active subjects.

Describe below or attach a document describing activity suspension, subject suspension, or any withdrawal procedures, as applicable.

Site is withdrawing completely from the study (also referred to as closing/terminating) with no plans to resume

* + - Submit a **Closure Report** (found on the IRB’s website) with this submission. All subjects must be safely withdrawn and/or transfer procedures complete at the time of submission.

**Other**:

Possible actions in response to COVID-19 could include:

* Addition of pre-screening questionnaires to exclude persons who display symptoms of COVID-19 or are at high risk of having been exposed to COVID-19
* Decreasing protocol mandated in-person study visits
* Allowing wider visit windows
* Replacing protocol mandated in-person study visits with one or more of the following:
* phone calls
* home visits
* telemedicine virtual visits
* implement digital technology to record symptoms
* Allowing blood draws at remote or commercial laboratories
* Shipping investigational products directly to research participants

*Please note that shipment of investigational products to research participants is subject to state and federal laws*

* Other