

Sponsor Visits During COVID-19 Clinical Research Restart

As a result of the COVID-19 pandemic, many of you have had to postpone required Study Sponsor visits (site initiation, auditing and monitoring). Effective immediately, these visits by Study Sponsor Personnel will be allowed to proceed if the following three criteria are met:

1. The study sponsor is unable to perform the required tasks via remote access or teleconference.
2. The BCH Study Team accepts and performs the following responsibilities:

BCH Study Team Responsibilities			
Before arriving	Upon arrival	During the visit	At conclusion of visit
<ul style="list-style-type: none"> • Schedule an appointment: <ul style="list-style-type: none"> ○ Confirm the appointment is allowable at intended location ○ Confirm current BCH occupancy guidelines can be followed • Share the BCH COVID-19 guidelines and educational material with the visitor, such as: <ul style="list-style-type: none"> ○ PowerPoint BCH COVID-19 training material ○ Research Visitor policy ○ Other training material 	<ul style="list-style-type: none"> • Confirm visitor identity • Confirm visitor has completed the attestation and is wearing a hospital issued mask. • Confirm visitor has reviewed the BCH COVID-19 guidelines/materials in advance of arrival • Escort visitor to their appointment location 	<ul style="list-style-type: none"> • Ensure visitor complies with all BCH policies and guidelines, such as: <ul style="list-style-type: none"> ○ Wearing a hospital issued mask at all times. ○ Maintain 6 foot distancing. 	<ul style="list-style-type: none"> • Escort the visitor out of the building.

3. The Study Sponsor-Personnel accepts and performs the following responsibilities:

Sponsor-personnel Expendabilities			
Before arriving	Upon arrival	During the visit	At conclusion of visit
<ul style="list-style-type: none"> • Confirms a pre-scheduled appointment with BCH personnel. • Review the BCH COVID-19 guidelines and educational materials provided by BCH staff. • Attest to their health prior to entry. <ul style="list-style-type: none"> ○ Attestation includes that they have not tested positive, been around anyone who is suspected or test positive or show any signs and symptoms for COVID-19. 	<ul style="list-style-type: none"> • Obtain and wear a hospital issued mask while in BCH facilities. • Follow the re-entry protocols. • Should wait to be escorted from the building's entrance by a BCH Study Team member. 	<ul style="list-style-type: none"> • Follow the protocols and maintain social distancing procedures in the building including lobbies, elevators, labs, office spaces, etc. 	<ul style="list-style-type: none"> • After work is completed and prior to leaving, wash hands with soap and water. • Report to OHS if any COVID-19 symptoms develop.