



## Roswell Park FAQ for Clinical Research Sponsors: COVID-19

*This is a living document, and is subject to change at any time. We encourage sponsors to check the [Roswell Park.org](http://RoswellPark.org) website page to get up to date information on Roswell's response plan. In addition, sponsors are encouraged to discuss study specific action plans with the local Investigator and Study team. These process adjustments may supersede Clinical Research Services Departmental policies during the COVID-19 Pandemic.*

### 1. Is Roswell Park allowing on-site monitoring visits at this time?

Currently we are not able to accommodate on-site monitoring visits. External monitors often travel from institution to institution and from city to city. To safeguard our patients and staff, and to safeguard external monitors, no monitoring visits will take place on site until further notice. This is a measure to prevent the possibility of spread of the coronavirus disease to a particularly vulnerable patient population, and to the staff that provide care, conduct and collect research data.

### 2. Is remote monitoring available at Roswell Park?

Roswell Park is limited in the number of remote access permissions we are able to provide. We will prioritize requests based on studies that have enrolled the first patient and those that are scheduled for data lock. Telephone calls with staff during regular business hours may be allowed if staff is sufficient to work through prioritization of requests. Alternatively, you may reach out to: [monitorvisits@roswellpark.org](mailto:monitorvisits@roswellpark.org). We are doing our best to prioritize and review emails requests that are received.

### 3. Does your site have any plans of stopping recruitment activities?

PI's will be in communication with study sponsors to make determination for what studies will continue to be conducted given the staffing and resources available. Our primary concern is for patient and staff safety. PI's/study teams will be in communication with study sponsors regarding possible suspension of recruitment where possible, however recruitment may continue based on Investigator judgement and approval from Research Leadership within the Department of Clinical Research Services (CRS), taking into consideration what is best for their patient, with adherence to the CDC Guidelines. In addition, in cases where recruitment remains active, sponsors should anticipate a reduction in overall rate of enrollment.

### 4. What should be expected for any patients currently in screening?

For any patient currently in screening, the patient may continue to be screened/enrolled, based on the Investigator's judgement and discussion with CRS Leadership regarding the diminished staff capabilities.



## 5. Does your site have any plans that will affect active patients and their study visits?

Patients currently receiving treatment on an active trial will continue to be treated in accordance with the FDA and IRB Guidelines. Sponsors and Investigators should evaluate whether alternative methods for assessments or notification of new information to participants could be implemented in an alternate fashion to assure safety of participants and staff. Such changes to the protocol or investigational plan to minimize or eliminate immediate hazards or to protect the life and well-being of research participants (e.g., to limit exposure to COVID-19) may be implemented without IRB approval or before filing an amendment to the IND or IDE, but are required to be reported afterward.

Investigators will use all reasonable efforts to manage the patient according to the written protocol however; patient safety will supersede protocol compliance. It is possible, and probable, that select study visits may be completed remotely, or if necessary, omitted. In cases where all protocol requirements can be reasonably completed, priority will be placed on collecting the protocol elements for safety, and primary end point measures. Sponsors should expect missed data due to missed visits, and deviations resulting from changes in how patients are being evaluated (e.g. telephone calls rather than on-site). It is also likely that Roswell Park equipment may be used instead of sponsor provided equipment as deemed appropriate. Research and/or safety laboratory testing could be delayed or eliminated based on diminished capacity of resources. For research personnel safety, studies that require central lab kit collection and processing may be eliminated or performed locally.

## 6. Is there an increased possibility that patients will not be able to travel to the hospital for their visits?

Yes. We serve patients from across Western New York, out of state and out of country. It is possible that patients may not be able to commute this considerable distance to the hospital due to their own illness, a caregiver's illness, or generalized concerns about entering the hospital, or a large urban area. The Investigator and study team will make all efforts to support the patient with coming to Roswell Park where appropriate and will source alternative solutions to complete the protocol requirements where appropriate. However, sponsors should expect missed data due to missed visits, and deviations resulting from changes in how patients are being evaluated (e.g. telephone calls rather than on-site).

## 7. What are some of the possible contingency plans your site has in cases where a patient is unable/should not come into the hospital for a research visit?

While not limited to the points below, in cases where a patient cannot or should not be coming to the hospital, the following options may be appropriate to ensure completion of clinical trial protocol requirements taking into account any PI and/or sponsor provided guidance:

1. **Oral IP dispensing:** Delivery to the patient's home by courier, based on product stability, and cost recovery availability.
2. **Oral Accountability:** Routine phone calls with the patient for verbal confirmation of accountability, pill diaries, with reconciliation once the patient is able to return to the site.



3. **Central Safety Labs:** Roswell Park Dept. of Pathology and Laboratory Medicine Services including the Clinical Research Support Laboratory are running on a diminished capacity. Site staff will be in communication with Sponsors to advise on alternate processing, testing, or courier solutions to help our site maintain the continuity of clinical trial testing given resource availability.
4. **Medical Imaging:** CT, MRIs, PET Scans will continue to be provided at Roswell Park for clinical trial purposes taking into account PI and patient discussions. If tests or procedures are delayed or missed, or provided outside of listed sites on the FDA 1572, this will be noted in the study files as a deviation related to the COVID-19 Crisis.
5. **Quality of Life Questionnaires:** In cases where a patient does not require additional onsite activities, QoL assessments will be completed remotely, either as a package provided at an earlier onsite visit, via mail, or electronically.
6. **Data Entry:** Roswell Park will make every effort to adhere to the agreed upon data entry and query guidelines provided at study start up as staffing and resources allow however, eligibility and safety data will be given priority. Our site may request data extensions related to delayed visits, or for data points and queries that are not directly associated with safety or eligibility
7. **Consenting/Participant notification of new information:** New Study consenting, updated consent addendums, patient letters, or other notification of significant new information may be communicated to participants remotely and documented in the medical record in lieu of participants returning a signed document to the site.

## 8. Do you anticipate any delays with initiating new studies?

Roswell Park will continue to process new studies through the Scientific Review Committee and Institutional Review Board based on available of committee members charged with reviewing studies. We do expect delays in activating new studies given the reduction in available human resources due to COVID-19 infection, isolation, or redeployment of staff to support hospital operations therefore, we will be holding activations of new studies effective 3/18/20. We will work with our Investigators and Clinical Disease teams to prioritize studies considered to be essential treatment options for our patients with an unmet need. This will be challenging, as we value research and realize the overarching benefit to all our patients to have a wide variety of options available. Any trial not selected for activation, will be activated as resources are slowly restored and with consultation with the PI's and Senior Leadership input.

In addition, to manage available resources, activation efforts are to be allocated to studies deemed to be essential for our patients focusing on COVID-19 research.

## 9. Will there be any impact on submitting Protocol Amendments to your IRB's?

Submission of amendments may be delayed based on staff availability but will continue. Any amendment pertaining to COVID-19 will be prioritized. If you have any questions or concerns about the status of any amendment, please reach out to your Regulatory Coordinator and/or PI, or contact our Sr. Administrator Study submissions & Regulatory Affairs at [Virginia.Doran@roswellpark.org](mailto:Virginia.Doran@roswellpark.org).