Q: How is ECOG-ACRIN addressing protocol deviations? Example: lab draws and start times for treatments, which are often delayed in light of the COVID-19 hurdles.

A: Protocol deviations related to COVID-19 need to be tracked and clearly documented as being related to COVID-19. While the NCI Central IRB (CIRB) or local IRBs may require submission of deviations more frequently, EA is requesting that the logs be submitted within one month after the period when COVID-19 guidance is in effect (currently June 14, 2020, subject to change). Many deviations which would typically be considered major, may not be treated as major during this period if related to COVID-19.

Q: Is there a pause on opening up new trials?

A: No. The activation of new trials is continuing during this time so that new protocols will be open and ready as options for patients. EA is reviewing new activations on a case by case basis, and if it makes sense, we will activate the trial. However, if there are unique features in the design of the trial, we may delay activation until a later time.

Q: Since ECOG-ACRIN will continue activating new studies is it safe to assume the NCI CIRB is reviewing new studies? Or will these have to go through a site’s local IRB?

A: The NCI CIRB continues to review new studies and complete continuing reviews for trials. There is no change in the oversight and responsibilities of the CIRB.

Q: Specimen collection not impacting patient treatment. There seems to be wide variability on institutional practices on specimen collection, probably dictated by the severity of COVID-19 at their site. What is ECOG-ACRIN’s stance on that? Small sites with limited staff in the labs may face particular limitations regarding getting bio-specimens during the pandemic.

A: Sites are encouraged to obtain specimens, but it is understood during the pandemic that some specimens may be missed. Local labs that are more convenient for the patient may be an option in some situations as well. Otherwise, sites are encouraged to reach out via the EACOVID19@ecog-acrin.org email address to confirm whether a particular specimen is critical to study outcome or patient safety. If so, then those specimens should be prioritized to obtain, even if late, rather than missed entirely. For additional information, the COVID-19 Information
pages on both the CTSU and EA Members website contain all protocol-specific memos related to specimen submissions.

Q: Investigational drug pharmacists – Small satellites and rural sites potentially have only one pharmacist who can mix and dispense investigational agents. If that pharmacist is out due to illness or furlough and the drug cannot be dispensed for a cycle of treatment, would that be a MAJOR or just a MINOR deviation during the pandemic? When a site is completely dependent on one specially trained employee, it makes small sites potentially vulnerable to unavoidable deviations during the pandemic.

A: There are a few other options, though none may work in this situation. One would be to administer the investigational agent at another participating site and transfer the patient. Another may be that if the location is a satellite, perhaps the dose could be administered at the main study site, or if product stability permits, the dose could be prepared at the main study site and couriered to the satellite. If none of those options are feasible, then it may be unavoidable to miss a dose of the investigational agent. This needs to be clearly documented along with the circumstances.

Q: Can you provide guidance on data delinquencies, delays in scheduling follow-up visits, or missed procedures and assessments. How should sites document this? How will this impact performance monitoring?

A: Delays related directly to COVID-19 or related local restrictions should be clearly documented as such. While some of these are considered deviations, the association to COVID-19 will be taken into account. While CIRB or local IRBs may require submission of deviations more frequently, EA is requesting that deviation logs related to COVID-19 be submitted within one month after the period when COVID-19 guidance is in effect (currently June 14, 2020, subject to change).

With respect to impact on performance monitoring, EA will not be conducting the Quarterly Performance Monitoring scheduled to be run for the spring 2020 quarter. An announcement about this will be released this week.

Q: We’ve received guidance about dispensing IP, suggestions for alternative delivery methods, etc. How should sites handle IP returns since it requires greater levels of interaction and therefore exposure?

A: For documenting patient compliance, it may be permissible for the patient to count the medication at home while on video chat, take pictures of empty bottles, or take pictures of
diaries to text or email to the site. The substitute method used to monitor compliance should be documented in the records. Re: IP return, please contact EACOVID19@ecog-acrin.org.

Q: Should sites anticipate delays in study reimbursements? Can you speak to how this will affect both NCORPs/LAPs and Main Member sites?

A: NCORP, LAPs and Main Member sites should not anticipate any delays in study reimbursements coming from ECOG-ACRIN.

Q: I know the NCI doesn’t get involved with research HIPAA procedures, but I am curious to know if sites are obtaining HIPAA waivers from their Privacy Board.

A: Please refer to the latest guidance from HHS as limited waivers of HIPAA Sanctions are being permitted due to the National Public Health Emergency: https://www.hhs.gov/sites/default/files/hipaa-and-covid-19-limited-hipaa-waiver-bulletin-508.pdf

Q: Remote consenting – it seems it is allowed, but the NCI CIRB guidelines say the Responsible Investigator needs to conduct the entire consent process and have a witness present during the call. The witness would presumably be a CRA or research nurse. This is different than what the Delegation of Tasks Log allows. Those allow for a designee (such as a CRA or research nurse) to be delegated to conduct the informed consent process. If the investigator is expected to go through the entire consent form remotely instead of allowing a CRA or research nurse to do that, it might discourage investigators from consenting patients remotely – especially if the process requires an investigator to conduct the entire process and have a witness there for the whole discussion. What is ECOG-ACRIN’s policy regarding remote consenting?

A: The investigator OR DESIGNEE can conduct the remote consent process, however, sites should follow their standard practice.

EA supports the remote consent process utilizing telemedicine to assist in the patient consent process. This work practice requires a potential patient to receive a copy of the consent in advance of the consent discussion. The consent must be signed by the patient and the researcher leading the consent discussion (dates do not need to be the same but the patient needs to sign first). A witness should be present but is not mandated per FDA guidance. A detailed consent note in the patient’s research file is also required to document the process.

Q: What is the definition of “witness” when using the remote consent process?
A: The FDA, OHRP, and NCI CIRB do not provide explicit guidance on who can serve as a witness during the informed consent process for clinical research. An impartial judge is recommended. Family members serving as witnesses are discouraged. Please confirm with your local IRB as to who can serve as witness during the remote consent process.