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TO: ALL NATIONAL CLINICAL TRIALS NETWORK (NCTN) MEMBERS AND NCORP COMPONENTS AND SUBCOMPONENTS

FROM: SWOG Operations Office (E-mail: protocols@swog.org)

RE: Interim COVID-19 Guidance for Eligibility Visits and H&P Assessments

MEMORANDUM – Interim COVID-19 Guidance for Eligibility Visits and H&P Assessments

Subsequent to receipt of site questions regarding applicability of the NCI-specified allowances to eligibility visits and SWOG communications with the NCI Protocol Information Office, the purpose of this memorandum is to better highlight the intent of the NCI guidance, which is specified at the onset of the [March 23, 2020 NCI guidance memorandum](#).

The March 23, 2020 NCI guidance memorandum provides allowances for phone or videoconferencing to be utilized for telemedicine/virtual visits as an alternative procedure “that may be implemented to maintain the safety and continuity of care for **patients enrolled on ongoing clinical trials** supported by CTEP and the NCORP that are being affected by the spread of the novel coronavirus.” Similarly, per the March 23, 2020 NCI guidance memorandum, “study visits” are visits that are required for enrolled patients’ ongoing continuity of care. Herein, the term “study visits” does **not** refer to an initial eligibility visit required for registration to an NCI protocol.

H&P Eligibility Assessment:

The History and Physical Exam, Performance Status, and Toxicity notation **for purposes of eligibility must be assessed via a patient visit**. It would **not** be reasonable (per NCI policy and guidance) to assess the patient for eligibility without a patient visit (The option for telemedicine assessment does not apply). However, in some special circumstances (e.g., in the rare case where a patient was already in the screening process for an NCI trial and the NCI trial was part of the planned patient care, wherein the conduct of history and physical exam for eligibility purposes is the sole remaining component that must be met prior to patient registration to an NCI trial), it could be appropriate to have the H&P conducted via a visit with a local healthcare provider, as per the [March 13, 2020 NCI guidance](#) and provided that all of the following criteria for determination, oversight, and documentation are met.

In the determination of the Responsible Investigator:

1. The risk/benefit of having the patient travel to the participating research site (Responsible Investigator’s location) **ONLY** for the purpose of the eligibility physical exam (H&P/PS/tox assessment) is **not** favorable to the patient, or patient travel to the participating research site (Responsible Investigator’s location) is not possible due to circumstance of COVID-19 travel restrictions; **and**
2. The benefit of having the physical exam conducted by a local healthcare provider outweighs the risks of exposure of the patient to the virus by travelling to the participating research site (Responsible Investigator’s location) for an in-person visit, **and**
3. The patient would subsequently be able to travel to the participating research site (Responsible Investigator location) for required protocol/treatment visits (i.e., that the risk/benefit of subsequent travel to the participating research site (Responsible Investigator’s location) for subsequent protocol-specified visits is also taken into careful consideration at the time of registration to the protocol).

IF all 3 of the above criteria are met, then, with consideration for the COVID-19 public health emergency, it would be reasonable for a Local Healthcare Investigator to provide the H&P visit as an intermittent/short-term care activity provided that the Responsible Investigator believes it is in the patient's best interest to complete the study activity (eligibility H&P) so that the patient can receive needed cancer treatment care on study, **and wherein:**

1. The Responsible Investigator determines that **the H&P visit can be adequately conducted by a local healthcare provider under the direct oversight of the Responsible Investigator** in accordance with the protocol, **and**
2. **Processes are in place to report all required information to the Responsible Investigator**, who is responsible for ensuring that the data is entered into the data management system for the trial, **and**
3. Both the rationale for why this had to be done by a Local Healthcare Provider and that it was done under the direct oversight of the Responsible Investigator per protocol requirements are **fully documented** in the medical record and research record of the patient.

H&P Assessments for Patients on Active Protocol Treatment:

Subsequent to repeat site questions regarding utilization of telemedicine/virtual visits as a means of conducting H&P for patients on active protocol treatment, this memorandum also serves to better highlight the criteria that must be met prior to implementation of a telemedicine/virtual visit for continuity of care:

1. The benefit of conduct of the visit via telemedicine/virtual visit **must** outweigh the risk of exposure to the patient to the virus by coming in for an additional in-person visit **solely for the purpose of H&P; and**
2. The Responsible Investigator determines that the telemedicine/virtual visit **is adequate to achieve the central purpose of the visit and ensure patient safety; and**
3. The rationale for conduct of H&P via telemedicine/virtual visit, assurances that the telemedicine/virtual visit was adequate to fulfill the central purpose of the visit, and any additional measures implemented to ensure patient safety must be thoroughly documented.

Of note: In event that H&P is conducted via telemedicine for a patient on active protocol treatment, and the patient will be undergoing laboratory (or similar) assessments at a separate visit (+/- 3 days of the H&P conducted via telemedicine/virtual visit), the patient's vital signs and weight should be obtained at the same time as the laboratory (or similar) assessments to ensure that the entire purpose of the H&P visit is fulfilled.

This memorandum serves to notify the NCI, CIRB, and SWOG Statistics and Data Management Center.

cc: PROTOCOL & INFORMATION OFFICE