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TO: ALL NATIONAL CANCER CLINICAL TRIALS NETWORK (NCTN) MEMBERS AND NATIONAL COMMUNITY ONCOLOGY RESEARCH PROGRAM (NCORP) AFFILIATES AND SUBAFFILIATES

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

RE: General Guidance for SWOG Clinical Trials and COVID-19 Vaccine

MEMORANDUM- General Guidance for SWOG Clinical Trials and COVID-19 Vaccine

The purpose of this memorandum is to provide general guidance regarding SWOG clinical trials and the COVID-19 vaccination. In conjunction with NCI's guidance, SWOG is providing the following general guidance regarding the currently available COVID-19 vaccinations (the Moderna and Pfizer vaccines, both of which received for emergency use authorization from FDA in December 2020).

- These vaccines are NOT considered investigational for the purposes of participation in SWOG clinical trials.
- The currently available COVID-19 vaccines do not contain live virus; therefore, COVID-19 vaccination would not preclude eligibility in SWOG clinical trials that exclude patients who have received live vaccines.
- Patients are not precluded from receiving the vaccine based on their current/ongoing participation in SWOG clinical trials. Note some specific considerations:
 - The co-administration of the COVID-19 vaccines with anti-cancer therapies is not well studied. Therefore, consideration should be given for each patient as to the appropriate timing for receiving vaccines. In particular, treating investigators are encouraged to consider:
 - whether and how immunotherapy administration should be spaced from COVID-19 vaccination,
 - whether an individual protocol disallows vaccine administration within a specified window of anti-cancer therapy administration (e.g., in some SWOG clinical trials, vaccines are contraindicated within a week of pembrolizumab dose administration).
 - The COVID-19 vaccine should be delivered to a limb with an intact lymph node basin; the vaccine should not be administered in a limb that has undergone lymphadenectomy (sentinel lymph node biopsy is acceptable).

Documentation of COVID-19 vaccination need only be submitted for a SWOG clinical trial if specifically requested by that individual trial; otherwise, there is no need for specific documentation regarding COVID-19 vaccine administration. If requested by an individual study, reporting/documentation should follow the guidance provided by that trial.

Please note that this is general guidance. Individual studies may provide additional or alternative guidance via a protocol-specific memorandum based on the protocol considerations. Those study-specific guidance memoranda should be referenced when determining whether and how vaccination is appropriate for participants currently enrolled or considering enrollment on SWOG clinical trials, and what COVID-19 vaccination documentation might be required for each trial.

cc: PROTOCOL & INFORMATION OFFICE