

July 1, 2020

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

FROM: SWOG Operations Office ([protocols@swog.org](mailto:protocols@swog.org))

RE: SWOG COVID-19 Diagnosis and Protocol Deviations Form

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**MEMORANDUM - SWOG COVID-19 Diagnosis and Protocol Deviations Form**

As mentioned in prior notifications, SWOG is collecting positive COVID-19 diagnoses and pandemic-related deviations for participants followed on SWOG-coordinated trials. The SWOG COVID-19 Diagnosis and Protocol Deviation Form is available now for every participant chart in Rave and the CRA Workbench (for pre-Rave studies).

To access in Rave, utilize the 'Add Event' drop-down located on the Subject Home Page for each participant. To access in the CRA Workbench, click on 'Forms' then the tab for 'Follow-Up' within the link for Pre-Rave Data Submission.

For a participant with a COVID-19 diagnosis, provide the date of the first positive test on this form. It is not necessary to report if they test positive again.

On April 20, sites were provided a SWOG COVID-19 Protocol Deviation Log to use as a tracking tool to record all pandemic-related deviations. Please transfer all documented major and minor deviations from this log (or other site-approved logs) to the SWOG COVID-19 Diagnosis and Protocol Deviation Form. It is not necessary to continue to maintain a Deviation Log going forward as long as there is sufficient documentation in the research record to support the reported data.

Any current or future deviations are expected to be reported on this form within 15 days of the event or when the site became aware of the event. The form in Rave may only be added once and sites can add additional log lines for subsequent deviations. Data Coordinators at the SWOG Data Operations Center have been tracking diagnoses and deviations noted on other forms in their ongoing reviews and will issue queries for sites to report them accordingly.

Detailed instructions are provided in the attached PDF. If you have further questions, please reach out to your Data Coordinator via one of the committee-specific email distribution lists below or by phone at 206-652-2267.

[BreastQuestion@crab.org](mailto:BreastQuestion@crab.org)  
[CancerControlQuestion@crab.org](mailto:CancerControlQuestion@crab.org)  
[GIquestion@crab.org](mailto:GIquestion@crab.org)  
[GUquestion@crab.org](mailto:GUquestion@crab.org)  
[LeukemiaQuestion@crab.org](mailto:LeukemiaQuestion@crab.org)

[LungQuestion@crab.org](mailto:LungQuestion@crab.org)  
[LymphomaQuestion@crab.org](mailto:LymphomaQuestion@crab.org)  
[MelanomaQuestion@crab.org](mailto:MelanomaQuestion@crab.org)  
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This memorandum serves to notify the NCI, CIRB, and SWOG Statistics and Data Management Center.

cc: PROTOCOL & INFORMATION OFFICE