Date:       December 01, 2023

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

FROM:       SWOG Network Operations Center (protocols@swog.org)

RE:         Personal Identifiable Information (PII) in OPEN

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## Personal Identifiable Information (PII) in OPEN

The collection of PII, specifically social security numbers (SSN) and hospital ID (HID) numbers, on any NCTN and NCORP protocols using OPEN should be limited to only what is necessary.  If necessary, there will be appropriate language in the study background and Informed Consent Document (ICD).  Other demographic information, including date of birth, will continue to be collected.

Effective immediately, CTSU has begun reviewing all studies for PII collection and will block the SSN and HID fields in OPEN, unless SSN or HID is necessary for trial objectives and participants have consented to collection of this information.

**New trial activations**:

If PII collection is identified, the study activation will be held until removal of all collection of SSN or HID unless strong justification is provided.

**Trials with active accrual:**

During recent conference calls with Group representatives, the NCI asked Groups to restrict further collection of PII in currently active trials. Steps being taken to remove PII include blocking the future collection of SSN and HID fields and scrubbing the information from the OPEN database.

**Trials closed to accrual / closed to accrual and treatment complete:**

Steps being taken to minimize storage of PII in currently closed trials include a onetime data export to each Network Group, and then scrubbing the information from the OPEN database.

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

cc:      PROTOCOL & INFORMATION OFFICE

4201 Medical Drive, Suite 250 | San Antonio, TX  78229 | OFFICE 210-614-8808 | FAX 210-614-0006

In partnership with    KNIGHT CANCER Institute OHSU    NCI National Clinical Trials Network    NCI Community Oncology Research Program