Baseline Abnormalities Form

(please also refer to the SWOG CRA Manual for Oncology Research Professionals: General Forms and Guidelines, Chapter 16)

Page: **Baseline Abnormalities - Baseline**

Did the patient have any abnormalities or conditions present PRIOR to protocol treatment?

If Yes, using CTCAE 4.0 Grade definitions, please report them below

If day of Start Date is unknown, please write "UN" in the day field. If month of Start Date is unknown, please select "UNK" from the dropdown menu.

#	Verbatim term	CTCAE(4.0) adverse event term	CTCAE(4.0) grade	Serious	Start date
1	Vertigo	Vertigo	1	No	UN Jun 2014
2	Hot flashes	Hot flashes	1	No	UN UNK 2007
3	Hyperglycemia	Hyperglycemia	1	No	13 May 2019
4	Hypercalcemia	Hypercalcemia	1	No	13 May 2019

- Some studies use a Baseline Abnormalities Form to document existing conditions or continuing toxicities caused by prior treatment.
  - The collection of this form, if required, will be noted in Sections 14.0 and 18.0 of the protocol.

- A baseline abnormality is defined by CTEP as any abnormal assessment (e.g., physical finding, subjective complaint, or diagnostic test abnormality) identified as part of the routine pre-study work-up for which a CTCAE term exists.

- The Adverse Event Code is the appropriate CTCAE code for a baseline abnormality.
  - The 'Other, Specify' options should only be used if there is not an appropriate adverse event term available.
  - While Pain is an acceptable CTCAEv4 term, Pain is also very generic. If this is the appropriate term to use, please specify site/type of pain in the Comments section at the bottom of the form.

- **The Baseline Abnormalities Form is not used as a place to record the patient's medical history, diagnosis and/or pre-existing condition. For example, prior tonsillectomy or ongoing diabetes should not be recorded.**