PR

ACRIN 6695

Perfusion Imaging as a Cancer Biomarker (GOG-0262)

Protocol Variation Form

If this is a revised or corrected form, please √ box. ☐

ACRIN Study 6695
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

1. Check the protocol deviation being reported: *(select only one)* [1]

- O 1 Inclusion/exclusion criteria not met at time of registration/randomization
- O 2 Imaging-related deviation (complete Q1b)
- O 3 Study activity performed without participant consent
- O 4 Visit or follow-up procedures not performed per protocol (specify visit in Q6)
- O 5 Case enrolled under expired IRB approval/FWA
- O 6 Participant did not meet the imaging criteria at T0 and was imaged
- O 7 Visit outside of timeframe specified in protocol
- O 88 Other, specify: _____ [2]

1b. Image related deviation: *(select only one)* [3]

- O 1 Scan not performed according to protocol specific guidelines
- O 2 Images lost/unavailable
- O 88 Other, specify: _____ [4]

2. Date the protocol deviation occurred: _____ - _____ - **20**____ (mm-dd-yyyy) [5]

3. Date the protocol deviation was discovered: _____ - _____ - **20**____ (mm-dd-yyyy) [6]

4. Describe the protocol deviation:

_____ [7]

_____ [8]

5. What was done to rectify the situation and/or prevent future occurrence:

_____ [9]

_____ [10]

6. Please provide the time point this study deviation applies to: *(check only one)* [11]

- O T0- Baseline/Eligibility CT
- O T1- 18-21 days into cycle 1
- O T2- 8-10 days into cycle 2

6a. Provide the visit / follow-up study procedure(s) this PR corresponds to *(check all that apply)*

- ☐ Non-enhanced CT [12]
- ☐ Assessment of non-enhanced CT [13]
- ☐ Localization CT [14]
- ☐ Perfusion CT [15]
- ☐ Repeat perfusion CT [16]
- ☐ RECIST [17]
- ☐ Exam dose [18]
- ☐ AE assessment [19]

_____ [20]
Initials of person responsible for data (RA, study staff)

_____ - _____ - _____ (mm-dd-yyyy) [21]
Date Form Completed

Investigator's signature _____ *(for external use only)*

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