ACRIN 6695
Forms Index

ACRIN 6695
Perfusion Imaging as a Cancer Biomarker (GOG-0262)

Form Version		Version Date
T0 - Registration Visit:		
T0	Eligibility/CT Perfusion Technical Assessment	v1.0 07-01-11
T1 - 18-21 days into Cycle 1:		
T1	Technical Assessment	v1.0 07-01-11
T2 - 8-10 days into Cycle 2:		
T2	T2 Technical Assessment	v1.0 07-01-11
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PR	Protocol Variation	v1.0 05-03-11
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SL	Clinical Rationale for Imaging Declination Form	v1.0 06-23-11

ITW

ACRIN 6695

Perfusion Imaging as a Cancer Biomarker (GOG-0262)

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

ACRIN Study 6695

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Please mail (with corresponding media) or fax this completed ITW to ACRIN
For further information or questions, please contact the ACRIN Imaging staff:

ACRIN
American College of Radiology
1818 Market Street - Suite 1600 - Philadelphia, PA 19103
Fax: 1-215-923-1737
imagearchive@acr.org

1. Time point: [1]

- ○ **Qualification Phantom Imaging (Complete Q2, Q3, Contact Info section)**
- ○ **T0**
- ○ **T1**
- ○ **T2**
- ○ **OTHER Imaging** _____ [2]
  (Complete Q10 and Contact Info section)

2. Mode of Image transmission: [3]

- ○ **CD/ DVD**
- ○ **Electronic Transfer (TRIAD)**

3. Date of Imaging: [4] _____ - _____ - _____ *mm-dd-yyyy*

Nonenhanced/ Eligibility CT Scan (T0 only)

4. Was the nonenhanced CT Scan performed/submitted? [5]

- ○ **No**
- ○ **Yes**
  - **a. Series #** _____ [6] **Image #'s** _____ [7]
  - **b. Series #** _____ [8] **Image #'s** _____ [9]
  - **c. Series #** _____ [10] **Image #'s** _____ [11]
  - **d. Series #** _____ [12] **Image #'s** _____ [13]
  - **e. Series #** _____ [14] **Image #'s** _____ [15]
  - **f. Series #** _____ [16] **Image #'s** _____ [17]

Comments: _____ [18]

5. Did you send a screencapture image of the tumor with measurements? [19]

- ○ **No**
- ○ **Yes** **a. Series #** _____ [20] **Image #'s** _____ [21]

This image is representative of tumor used for perfusion CT

Comments: _____ [22]

ITW

ACRIN 6695

Perfusion Imaging as a Cancer Biomarker (GOG-0262)

ACRIN Study 6695

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

Perfusion CT Scan

6. Was targeted localization non-enhanced CT scan done prior to acquiring Perfusion CT? [23]

○ No
○ Yes
a. Series # _____ [24] Image #'s _____ [25]
b. Series # _____ [26] Image #'s _____ [27]
c. Series # _____ [28] Image #'s _____ [29]

Comments: _____ [30]

7. Was the CT perfusion scan performed/submitted? [31]

○ No
○ Yes
a. Series # _____ [32] Image #'s _____ [33]

Comments: _____ [34]

8. Was targeted localization non-enhanced CT scan done prior to acquiring repeat Perfusion CT? [35]

○ No
○ Yes
a. Series # _____ [36] Image #'s _____ [37]
b. Series # _____ [38] Image #'s _____ [39]
c. Series # _____ [40] Image #'s _____ [41]

Comments: _____ [42]

9. Was repeat CT perfusion scan perform submitted? [43]

○ No
○ Yes

Comments: _____ [44]

Contrast Enhanced RECIST scan

10. Was a RECIST scan performed/submitted as part of this imaging? [45]

○ No
○ Yes
a. Series # _____ [46] Image #'s _____ [47]
b. Series # _____ [48] Image #'s _____ [49]
c. Series # _____ [50] Image #'s _____ [51]
d. Series # _____ [52] Image #'s _____ [53]
e. Series # _____ [54] Image #'s _____ [55]
f. Series # _____ [56] Image #'s _____ [57]

Comments: _____ [58]

Contact Information section

Screencaptured anonymized dose report/patient protocol as well as a screencapture of the targeted tumor must be included.

Comments: _____ [59]

_____
Name of Person(s) Completing This Form [60]

_____ - _____ - _____ *mm-dd-yyyy*
Date Form Completed [61]

_____
Email: [62]

_____
Phone: [63]

OI

ACRIN 6695

Perfusion Imaging as a Cancer Biomarker (GOG-0262)

Off-Imaging 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. **Date participant taken off imaging:**[1] _____ - _____ - _____ *mm-dd-yyyy*

2. **Reason for off-imaging**[2]**:**

O Participant withdrew consent

O Participant death *(specify date and cause below)*

Date of Death:[3] _____ - _____ - _____ *mm-dd-yyyy*

Cause of Death:[4]

O Disease Progression

O Other, specify:_____[5]

O Participant unable to complete imaging studies

Due to: ☐ Participant taken off GOG trial[6]

☐ Participant health[7]

☐ Other participant reason[8]

☐ Site-related reason[9]

☐ Metformin unable to be withheld for T2 imaging[10]

☐ Participant has a new contraindication to iodinated contrast[11]

Describe:_____[12]

_____[13]

O Participant did not meet target lesion requirements at T0

Requirement(s) not met: ☐ Minimum length of 1 cm in both long and short axis[14]

☐ Attenuation of at least 50% of target lesion is at least 10 HU on pre-contrast scan[15]

☐ Enhancement of at least 50% of target lesion is at least 5 HU on perfusion scan[16]

3. **Did the participant continue on the GOG-0262 study?**[17]

O No

O Yes

_____[18]
Initials of Person(s) Completing This Form

_____ - _____ - _____ (mm-dd-yyyy)[19]
Date Form Completed

Signature of Person Completing This Form _____ **(for external use only)**

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)*

SL

ACRIN 6695

Perfusion Imaging as a Cancer Biomarker (GOG-0262)

Clinical Rationale for Imaging Declination Form

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

ACRIN Study 6695

Institution _____ **GOG Case No.** _____

Participant Initials _____

1. Date participant enrolled into the GOG 0262 study: _____-_____-_____ *mm-dd-yyyy*

2. Date clinician met with participant for ACRIN 6695 participation: _____-_____-_____ *mm-dd-yyyy*

3. Did the participant agree to enroll into the ACRIN 6695 study?

- O If Yes, date participant enrolled into the study _____-_____-_____ *mm-dd-yyyy*
  Please sign and date form
- O If No, please complete entire SL form and fax a copy of the completed form to ACRIN (215-717-0936)

4. Reason for non participation

4a. Primary *(check one)*

- O Ineligible *(complete Q4c)*
- O Scheduling conflict between protocol
- O No desire to participate in research
- O Preference for standard treatment
- O Patient preferred another trial
- O Lack of awareness/education about trials
- O Perceived/possible side effects
- O Number/Length of imaging exams
- O Adverse to injection/needles
- O Claustrophobic
- O Cultural/religious issues
- O No insurance coverage
- O Financial concerns/indirect costs
- O Travel and transportation issues
- O Social issues (housing, childcare, etc)
- O Family member influenced against trial participation
- O Language barrier/lack of access to interpreter
- O Insurance company issue(s)
- O Medical Reason
- O Trial commitment length
- O Physician influenced against trial participation
- O Other

4b. Secondary *(check all that apply)*

- ☐ Ineligible *(complete Q4c)*
- ☐ Scheduling conflict between protocol
- ☐ No desire to participate in research
- ☐ Preference for standard treatment
- ☐ Patient preferred another trial
- ☐ Lack of awareness/education about trials
- ☐ Perceived/possible side effects
- ☐ Number/Length of imaging exams
- ☐ Adverse to injection/needles
- ☐ Claustrophobic
- ☐ Cultural/religious issues
- ☐ No insurance coverage
- ☐ Financial concerns/indirect costs
- ☐ Travel and transportation issues
- ☐ Social issues (housing, childcare, etc)
- ☐ Family member influenced against trial participation
- ☐ Language barrier/lack of access to interpreter
- ☐ Insurance company issue(s)
- ☐ Medical Reason
- ☐ Trial commitment length
- ☐ Physician influenced against trial participation
- ☐ Other

4c. If ineligible, check reason(s)

- ☐ Patients began GOG-0262 protocol treatment prior to being identified for 6695
- ☐ Patient has contraindication to iodinated contrast for perfusion CT imaging
- ☐ Patients would receive Metformin within 48 hours of perfusion CT imaging
- ☐ Tumor size

5. Did the clinician explain the scientific rationale for the ACRIN 6695 study to the participant?

- O Yes
- O No

SL

ACRIN 6695

Perfusion Imaging as a Cancer Biomarker (GOG-0262)

Clinical Rationale for Imaging Declination Form

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

ACRIN Study 6695

Institution _____ **GOG Case No.** _____

Participant Initials _____

6. As per this discussion, what was the description of the scientific rationale for the ACRIN 6695 study?

_____

_____

_____

7. Did the clinician explain the reasoning behind using perfusion CT as the imaging modality?

O Yes
O No

8. As per this discussion, what was the description of the rationale behind using perfusion CT?

_____

_____

_____

9. Did the clinician explain the reasoning behind the imaging time points for the ACRIN 6695 study?

O Yes
O No

10. As per this discussion, what was the description of the reasoning behind these timepoints?

_____

_____

_____

11. Did the clinician identify these perfusion CT timepoints and their alignment with GOG-0262 study?

O Yes
O No

12. As per this discussion, when can perfusion CT (T0) take place?

_____

_____

_____

13. As per this discussion, when can perfusion CT (T1) take place?

_____

_____

_____

14. As per this discussion, when can perfusion CT (T2) take place?

_____

_____

_____

15. Did the clinician explain the risks from participating in the ACRIN 6695 study?

O Yes
O No

SL

ACRIN 6695

Perfusion Imaging as a Cancer Biomarker (GOG-0262)

Clinical Rationale for Imaging Declination Form

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

ACRIN Study 6695

Institution _____ **GOG Case No.** _____

Participant Initials _____

16. As per this discussion, what are the risks from participating in the ACRIN 6695 study?

_____

_____

_____

17. Did the clinician explain the benefits from participating in the ACRIN 6695 study?

O Yes
O No

18. As described in this discussion, what are the risks from participating in the ACRIN 6695 study?

_____

_____

_____

19. Was the participant eligible to participate in the ACRIN 6695 study?

O Yes
O If No, why was the patient ineligible?

_____

_____

_____

20. Was a scheduling conflict identified that prohibited participation in the ACRIN 6695 study?

O If yes, what was the conflict?

_____

_____

_____

O No

21. Was the participant interested in participation in research studies?

O Yes
O If No, what reasons cited for disinterest?

_____

_____

_____

22. Is the participant interested in participation in other research studies?

O Yes
O No

23. Is the participant planning to enroll in a different research study?

O If Yes, what study? _____
O No

24. Did the participant continue on the GOG-0262 study?

O Yes
O No

SL

ACRIN 6695

Perfusion Imaging as a Cancer Biomarker (GOG-0262)

Clinical Rationale for Imaging Declination Form

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

ACRIN Study 6695

Institution _____ **GOG Case No.** _____

Participant Initials _____

25. Did the participant identify any perceived/ possible side effects from participating in the ACRIN 6695 study?

O If yes, what were these precived possible side effects?

_____

_____

_____

O No

26. Did the participant identify any concerns on the number of imaging exams?

O If yes, what were these concerns?

_____

_____

_____

O No

27. Did the participant identify any concerns to the injection of contrast agents?

O If yes, what were these concerns?

_____

_____

_____

O No

28. Did the participant express any cultural/religious issues?

O If yes, what were these concerns?

_____

_____

_____

O No

_____ _____-_____-_____

Initials of Person Completing This Form Date Form Completed *mm-dd-yyyy*

_____ _____-_____-_____

Initials of Person Completing This Form Date Form Completed *mm-dd-yyyy*

Signature of Person Completing This Form_____

Signature of Person Completing This Form_____

T0

ACRIN 6695

Perfusion Imaging as a Cancer Biomarker (GOG-0262)
Baseline Eligibility CT/Perfusion Imaging

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

ACRIN Study 6695
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Part I. Imaging Visit Details *Completed by Research Nurse/ ACRIN RA*

1. Date of Visit: _____-_____-_____ *mm-dd-yyyy* [1]

2. Was imaging initiated? [2]

O **No,** *check reason then initial and date form* [3]
- O **Scheduling problem**
- O **Participant death**
- O **Equipment failure**
- O **Participant refusal**
- O **Medical reason**
- O **Injection site complications**
- O **Claustrophobia**
- O **Adverse event**
- O **Participant withdrew consent**
- O **Other, specify:** _____ [4]

O **Yes**

3. Weight: [5] _____ O **kg** O lb [6]

4. Height: [7] _____ O **cm** O in [8]

5. Has the scanner used for this study been qualified by ACRIN? [9]
O **No** — **If no, provide reason** _____ [10]
O **Yes**

6. Was a prior RECIST scan done? [11]
O **No,** *Note: It is recommended the pt has RECIST following CT perfusion*
O **Yes**

Part II. Nonenhanced CT Scan *Completed by the Technologist*

7. Was oral contrast administered? [12]
O **No**
O **Yes,** *provide details:*
- **Type:** [13] O **Positive** O **Negative**
- **Contrast Brand:** _____ [14]
- **Amount:** _____ [15] O mg/mL [16] O other, ____ [17]
- **Time given:** ___ ___ : ___ ___ *hh:mm* [18]

8. Was the non-enhanced CT Scan performed? [19]
O **No**
O **Yes,** *provide details:*
- **a. Helical Scan?** [20] O **No** O **Yes**
- **b. Scan must be done with free breathing, please confirm:** [21] O **Not confirmed** O **Confirmed**
- **c. Dose-Length Product:** [22] _____ O **mGy-cm** [23]
- **d. $CTDI_{vol}$:** [24] _____ O **mGy** [25]

Part III. Eligibility Assessment *Must be Performed by Radiologist*

9. Did the participant have a target lesion at least 1cm in both long and short axis? [26]
O **No,** *Pt should not continue to CT Perfusion. Initial and date form*
O **Yes,** *provide details:*
- **a. Cranial-caudal dimension (z-axis):** _____**mm** [27]
- **Long axis:** _____**mm** [28]
- **Short axis:** _____**mm** [29]
- **@ Series #** _____ [30] **Image #** _____ [31]

10. Was the attenuation of at least 50% of the target lesion >10 HU? [32]
O **No,** *Pt should not continue to CT Perfusion. Initial and date form*
O **Yes**

T0

ACRIN 6695

Perfusion Imaging as a Cancer Biomarker (GOG-0262)
Baseline Eligibility CT/Perfusion imaging

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

ACRIN Study 6695

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Part IV. Perfusion CT Scan *Completed by the Technologist*

11. Was a targeted localization done? [33]
NOTE: Perform localization at 1/3 of dose

O **No**
O **Yes,** *provide details:*

a. **Helical Scan?** [34] O **No** O **Yes**
b. **Scan must be done with free breathing, please confirm:** [35] O **Not confirmed** O **Confirmed**
c. **Dose-Length Product:** [36] _____ O **mGy-cm** [37]
d. **$CTDI_{vol}$:** [38] _____ O **mGy** [39]
e. **Series #** ____ [40] **Image #** ____ [41] ***to*** **Series #** ____ [42] **Image #** ____ [43]

12. Was IV contrast administered? [44]

O **No**
O **Yes,** *provide details:*

a. **Brand Name:** _____ [45]
b. **Concentration:** [46] O **300** O **320** O **350** O **370** O **Other,** ____ [47]
c. **Location of Injection:** [48] O **antecubital vein** O **Other, specify;** _____ [49]
d. **Dose given:** [50] _____ O **mL** [51] O **other,** _____ [52]
e. **Rate of injection:** [53] _____ O **mL/sec** [54] O **other,** _____ [55]
f. **Time given:** [56] ___ ___ : ___ ___ *hh:mm*

13. Was the CT perfusion scan performed? [57]

O **No**
O **Yes,** *provide details:*

a. **Series #** ____ [58] **Image #** ____ [59] ***to*** **Series #** ____ [60] **Image #** ____ [61]
b. **Scan performed per 6695 protocol:** [62] O **No** O **Yes**
c. **Dose-Length Product:** [63] _____ O **mGy-cm** [64]
d. **$CTDI_{vol}$:** [65] _____ O **mGy** [66]

Part V. Contrast-Enhanced RECIST Scan *Completed by the Technologist*

14. Was a RECIST scan performed as part of this imaging? [67]
If the patient has already had a RECIST scan, it should not be repeated.

RECIST scan should be done per standard site protocol, EXCEPT contrast dose must be reduced by the amount already given to the participant for the CT perfusion (Q12d)

O **No**
O **Yes,** *provide details:*

a. **Contrast Dose given:** [68] _____ O **mL** [69] O **other,** _____ [70]
b. **Rate of injection:** [71] _____ O **mL/sec** [72] O **other,** _____ [73]
c. **Time given:** [74] ___ ___ : ___ ___ *hh:mm*
d. **Helical Scan?** [75] O **No** O **Yes**
e. **Scan must be done with breath hold, please confirm:** [76] O **Not confirmed** O **Confirmed**
f. **Dose-Length Product:** [77] _____ O **mGy-cm** [78]
g. **$CTDI_{vol}$:** [79] _____ O **mGy** [80]

Part VI. Exam Radiation Dose and AE Assessment *Completed by the Technologist*

15. Total dose-length product for entire exam: [81] _____ O **mGy-cm** [82]

16. Total $CTDI_{vol}$ for entire exam: [83] _____ O **mGy** [84]

17. Did the participant experience any adverse events during imaging? [85]

O **No**
O **Yes**

_____ [86] **Initials of Technologist**

_____ [87] **Initials of Radiologist**

_____ [88] **Initials of Research Nurse/ ACRIN RA**

____ - ____ - ____ [89] **Date Form Completed**

T1

ACRIN 6695

Perfusion Imaging as a Cancer Biomarker (GOG-0262)
T1 CT/ Perfusion Imaging *18-21 Days into Cycle 1*

ACRIN Study 6695
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

Part I. Imaging Visit Details *Completed by Research Nurse/ ACRIN RA*

1. Date of Visit: _____-_____-_____ *mm-dd-yyyy* [1]

2. Was imaging initiated? [2]

- O **No,** *check reason in next column* [3]
  - O **Scheduling problem**
  - O **Participant death**
  - O **Equipment failure**
  - O **Participant refusal**
  - O **Medical reason**
  - O **Injection site complications**
  - O **Claustrophobia**
  - O **Adverse event**
  - O **Participant withdrew consent**
  - O **Other, specify:** _____ [4]
- O **Yes**

3. Weight: [5] _____ O **kg** [6] O lb

4. Height: [7] _____ O **cm** [8] O in

5. Has the scanner used for this study been qualified by ACRIN? [9]
O **No** — **If no, provide reason** _____ [10]
O **Yes**

Part II. Preparation Step *Completed by the Technologist*

6. Target lesion as identified in prior (T0) scan:

Non-enhanced CT eligibility scan
Series # _____ [90] **Image #** _____ [91] ***to*** **Series #** _____ [92] **Image #** _____ [93]
Perfusion CT scan
Series # _____ [94] **Image #** _____ [95] ***to*** **Series #** _____ [96] **Image #** _____ [97]

Part III. Perfusion CT Scan *Completed by the Technologist*

7. Was a targeted localization done? [33]
NOTE: Perform localization at 1/3 of dose

- O **No**
- O **Yes,** *provide details:*
  - **a. Helical Scan?** [34] O **No** O **Yes**
  - **b. Scan must be done with free breathing, please confirm:** [35] O **Not Confirmed** O **Confirmed**
  - **c. Dose-Length Product:** [36] _____ O **mGy-cm** [37]
  - **d. $CTDI_{vol}$:** [38] _____ O **mGy** [39]
  - **e. Series #** _____ [40] **Image #** _____ [41] ***to*** **Series #** _____ [42] **Image #** _____ [43]

8. Was IV contrast administered? [44]

- O **No**
- O **Yes,** *provide details:*
  - **a. Brand Name:** _____ [45]
  - **b. Concentration:** [46] O **300** O **320** O **350** O **370** O **Other,** _____ [47]
  - **c. Location of Injection:** [48] O **antecubital vein** O **Other, specify;** _____ [49]
  - **d. Dose given:** [50] _____ O **mL** [51] O **other,** _____ [52]
  - **e. Rate of injection:** [53] _____ O **mL/sec** [54] O **other,** _____ [55]
  - **f. Time given:** ___ ___ : ___ ___ *hh:mm* [56]

9. Was the CT perfusion scan performed? [57]

- O **No**
- O **Yes,** *provide details:*
  - **a. Series #** _____ [58] **Image #** _____ [59] ***to*** **Series #** _____ [60] **Image #** _____ [61]
  - **b. Scan performed per 6695 protocol:** [62] O **No** O **Yes**
  - **c. Dose-Length Product:** [63] _____ O **mGy-cm** [64]
  - **d. $CTDI_{vol}$:** [65] _____ O **mGy** [66]

T1

ACRIN 6695

Perfusion Imaging as a Cancer Biomarker (GOG-0262)
T1 CT/ Perfusion Imaging *18-21 Days into Cycle 1*

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

ACRIN Study 6695
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Part IV. Repeat Perfusion CT Scan *Completed by the Technologist*

Performed starting from the 3rd pt enrolled at a site until 15 pts total from all sites have been enrolled into this arm.

10. Was a targeted localization done? [106]
NOTE: Perform localization at 1/3 of dose

O **No**

O **Yes,** *provide details:*

a. **Helical Scan?** [107] O **No** O **Yes**
b. **Scan must be done with free breathing, please confirm:** [108] O **Not confirmed** O **Confirmed**
c. **Dose-Length Product:** [109] _____ O **mGy-cm** [110]
d. **CTDI$_{vol}$:** [111] _____ O **mGy** [112]
e. **Series #** ____ [113] **Image #** ____ [114] ***to*** **Series #** ____ [115] **Image #** ____ [116]

11. Was IV contrast administered? [117]

O **No**

O **Yes,** *provide details:*

a. **Brand Name:** _____ [118]
b. **Concentration:** [119] O **300** O **320** O **350** O **370** O **Other,** _____ [120]
c. **Location of Injection:** [121] O **antecubital vein** O **Other, specify;** _____ [122]
d. **Dose given:** [123] _____ _____ O **mL** [124] O **other,** _____ [125]
e. **Rate of injection:** [126] _____ O **mL/sec** [127] O **other,** _____ [128]
f. **Time given:** __ __ : __ __ *hh:mm* [129]

12. Was the CT perfusion scan performed? [130]

O **No**

O **Yes,** *provide details:*

a. **Series #** ____ [131] **Image #** ____ [132] ***to*** **Series #** ____ [133] **Image #** ____ [134]
b. **Scan performed per 6695 protocol:** [135] O **No** O **Yes**
c. **Dose-Length Product:** [136] _____ O **mGy-cm** [137]
d. **CTDI$_{vol}$:** [138] _____ O **mGy** [139]

Part V. Contrast-Enhanced RECIST scan *Completed by the Technologist*

13. Was a RECIST scan performed as part of this imaging? [67]

RECIST scan should be done per standard site protocol, EXCEPT contrast dose must be reduced by the amount already given to the participant for the CT perfusion (Q8d and 11d)

O **No**

O **Yes,** *provide details:*

a. **Contrast Dose given:** [68] _____ _____ O **mL** [69] O **other,** _____ [70]
b. **Rate of injection:** _____ [71] O **mL/sec** [72] O **other,** _____ [73]
c. **Time given:** __ __ : __ __ *hh:mm* [74]
d. **Helical Scan?** [75] O **No** O **Yes**
e. **Scan must be done with breath hold, please confirm:** [76] O **Not confirmed** O **Confirmed**
f. **Dose-Length Product:** [77] _____ O **mGy-cm** [78]
g. **CTDI$_{vol}$:** [79] _____ O **mGy** [80]

Part VI. Exam Radiation Dose and AE Assessment *Completed by the Technologist*

14. Total dose-length product for entire exam: [81] _____ O **mGy-cm** [82]

15. Total CTDI$_{vol}$ for entire exam: [83] _____ O **mGy** [84]

16. Did the participant experience any adverse events during imaging? [85]

O **No**

O **Yes**

_____ [86] **Initials of Technologist**
_____ [87] **Initials of Radiologist**
_____ [88] **Initials of Research Nurse/ ACRIN RA**
____ - ____ - ____ [89] **Date Form Completed**

T2

ACRIN 6695

Perfusion Imaging as a Cancer Biomarker (GOG-0262)
T2 CT/ Perfusion Imaging *8-10 Days into Cycle 2*

ACRIN Study 6695

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

Part I. Imaging Visit Details *Completed by Research Nurse/ ACRIN RA*

1. Date of Visit: _____-_____-_____ *mm-dd-yyyy* [1]

2. Was imaging initiated? [2]

O **No,** *check reason, then initial and date form* [3]
- O **Scheduling problem**
- O **Participant death**
- O **Equipment failure**
- O **Participant refusal**
- O **Medical reason**
- O **Injection site complications**
- O **Claustrophobia**
- O **Adverse event**
- O **Participant withdrew consent**
- O **Other, specify:** _____ [4]

O **Yes**

3. Weight: [5] _____ O **kg** [6] O lb

4. Height: [7] _____ O **cm** [8] O in

5. Has the scanner used for this study been qualified by ACRIN? [9]
O **No** **If no, provide reason** _____ [10]
O **Yes**

Part II. Preparation Step *Completed by the Technologist*

6. Target lesion as identified in prior (T0) scan:
Non-enhanced CT eligibility scan
Series #_____ [90] **Image #**_____ [91] ***to*** **Series #**_____ [92] **Image #**_____ [93]
Perfusion CT scan
Series #_____ [94] **Image #**_____ [95] ***to*** **Series #**_____ [96] **Image #**_____ [97]

7. Target lesion as identified in prior (T1) scan:
Targeted Localization Scan
Series #_____ [98] **Image #**_____ [99] ***to*** **Series #**_____ [100] **Image #**_____ [101]
Perfusion CT scan
Series #_____ [102] **Image #**_____ [103] ***to*** **Series #**_____ [104] **Image #**_____ [105]

Part III. Perfusion CT Scan *Completed by the Technologist*

8. Was a targeted localization done? [33]
NOTE: Perform localization at 1/3 of dose

O **No**

O **Yes,** *provide details:*
- **a. Helical Scan?** [34] O **No** O **Yes**
- **b. Scan must be done with free breathing, please confirm:** [35] O **Not confirmed** O **Confirmed**
- **c. Dose-Length Product:** [36] _____ O **mGy-cm** [37]
- **d. $CTDI_{vol}$:** [38] _____ O **mGy** [39]
- **e. Series #**_____ [40] **Image #**_____ [41] ***to*** **Series #**_____ [42] **Image #**_____ [43]

9. Was IV contrast administered? [44]

O **No**

O **Yes,** *provide details:*
- **a. Brand Name:** _____ [45]
- **b. Concentration:** [46] O **300** O **320** O **350** O **370** O **Other,**____ [47]
- **c. Location of Injection:** [48] O **antecubital vein** O **Other, specify;**_____ [49]
- **d. Dose given:** _____ [50] O **mL** [51] O **other,**_____ [52]
- **e. Rate of injection:** _____ [53] O **mL/sec** [54] O **other,**_____ [55]
- **f. Time given:** ___ ___ : ___ ___ *hh:mm* [56]

T2

ACRIN 6695

Perfusion Imaging as a Cancer Biomarker (GOG-0262)
T2 CT/ Perfusion Imaging *8-10 Days into Cycle 2*

ACRIN Study 6695

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

10. Was the CT perfusion scan performed? [57]

O **No**

O **Yes,** *provide details:*

a. Series #_____ [58] **Image #**_____ [59] ***to*** **Series #**_____ [60] **Image #**_____ [61]

b. Scan performed per 6695 protocol: [62] O **No** O **Yes**

c. Dose-Length Product: _____ [63] O **mGy-cm** [64]

d. CTDI$_{vol}$: [65] _____ O **mGy** [66]

Part IV. Contrast-Enhanced RECIST scan *Completed by the Technologist*

11. Was a RECIST scan performed as part of this imaging? [67]

RECIST scan should be done per standard site protocol, EXCEPT contrast dose must be reduced by the amount already given to the participant for the CT perfusion (Q8d)

O **No**

O **Yes,** *provide details:*

a. Contrast Dose given: [68] _____ O **mL** [69]
O **other,**_____ [70]

b. Rate of injection: [71] _____ O **mL/sec** [72]
O **other,**_____ [73]

c. Time given: [74] ___ ___ : ___ ___ *hh:mm*

d. Helical Scan? [75] O **No** O **Yes**

e. Scan must be done with breath hold, please confirm: [76]
O **Not confirmed** O **Confirmed**

f. Dose-Length Product: [77] _____ O **mGy-cm** [78]

g. CTDI$_{vol}$: [79] _____ O **mGy** [80]

Part V. Exam Radiation Dose and AE Assessment *Completed by the Technologist*

12. Total dose-length product for entire exam: [81] _____ O **mGy-cm** [82]

13. Total CTDI$_{vol}$ for entire exam: [83] _____ O **mGy** [84]

14. Did the participant experience any adverse events during imaging? [85]

O **No**

O **Yes**

_____ [86] **Initials of Technologist**

_____ [87] **Initials of Radiologist**

_____ [88] **Initials of Research Nurse/ ACRIN RA**

_____ - _____ - _____ [89] **Date Form Completed**