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

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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

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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

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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_____

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