Imaging Forms for Protocol 0825/6686 — Version Date

MRI Assessment

End of Study

Additional Forms

Enter the imaging data through the Data Center on the ACRIN website. All data should be entered within two weeks of the MRI. Any questions related to these forms should be directed to:

Jamie Downs
ACRIN Data Management Associate
jdowns@acr.arrs.org
(215) 574-3242

V1

ACRIN 6686/ RTOG 0825

Phase III Trial of Bevacizumab with Temozaolomide vs. Chemoradiation with Temozaolomide Advanced MRI Local Technical Assessment Form

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

ACRIN Study **6686**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: This form is to be completed by the Technologist for each timepoint specified in the protocol. The completed form is submitted to ACRIN via the web site www.acrin.org and the corresponding reports are mailed to American College of Radiology, ACRIN Data Management/6686, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as MM/DD/YYYY. All responses are required unless otherwise noted. All images are to be transmitted to ACRIN as detailed in the study protocol.

General Imaging Information

1. Clinical trial timepoint

- O Baseline
- O Week 3
- O Week 3 + 1 day
- O Week 10

2. Was advanced MRI imaging performed at this visit?

- O No *(Complete Q2a then initial and date form)*
- O Yes

2a. Reason imaging not performed *(check only one)*

- O Scheduling Problem
- O Equipment failure
- O Patient refusal
- O Medical contraindication
- O Injection site complications
- O Claustrophobia
- O Only standard imaging performed
- O Other, specify _____

3. Has the scanner used for this study been qualified by ACRIN?

- O No, specify reason _____
- O Yes

4. Date of advanced MRI: _____-_____-_____
(mm-dd-yyyy)

5. Subject weight (measured day of scan)

_____ _____ _____ . _____ **KG**

☐ Unknown

6. Subject height (measured day of scan)

_____ _____ _____ **CM**

☐ Unknown

7. Exam start time (military time) ___ ___ : ___ ___

8. Exam stop time (military time) ___ ___ : ___ ___

First Injection (DCE-MRI)

9. Brand of contrast agent injected *(check only one)*

- O Magnevist
- O Omniscan
- O ProHance
- O OptiMark
- O MultiHance*
- O Vasovist*
- O Other, Specify _____

**(Multihance and Vasovist are not permitted per protocol; a PR will be required)*

10. Time of injection (military time) ___ ___ : ___ ___

11. Rate of injection ____ ____ **cc/sec**

12. Volume of contrast injection _____ **cc**

13. Volume of saline injection _____ **cc**

Second Injection (DSC-MRI)

14. Was second injection performed?

- O No *(Initial and date form)*
- O Yes

15. Time of injection (military time) ___ ___ : ___ ___

16. Rate of injection ____ ____ **cc/sec**

17. Volume of contrast injection _____ **cc**

18. Volume of saline injection _____ **cc**

COMMENTS: _____

_____

_____ _____-_____-_____

Initials of person responsible for data — Date form completed (mm-dd-yyyy)

_____

Initials of person completing the form

DS

RTOG / ACRIN Study 0825/6686
Phase III Trial of Bevacizumab with Temozaolomide vs. Chemoradiation with TemozaolomideMRI Assessment
End of Study Disposition

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

ACRIN Study **6686**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

1. Provide reason for study disposition by selecting *one* of the following: [1]

- O 1 Protocol defined follow-up completed
- O 2 Participant lost to follow-up
- O 3 Participant refused follow-up / withdrew
- O 4 Death *(specify date and cause below)*

  Date of death: _____[2]/_____[3]/_____[4] *(mm/dd/yyyy)*

  Cause of death [5]

  - O 1 Disease Progression
  - O 88 Other, specify _____[6]
- O 5 Adverse Event / Side Effects / Complications
- O 6 Protocol violation: *(check all that apply)*

  - ☐ Did not meet eligibility[7]
  - ☐ Technical problems[8]
  - ☐ Related to study visits[9]
  - ☐ Related to imaging[10]
  - ☐ Related to randomization[11]
  - ☐ Other[12] *(specify below)*
- O 7 Disease progression
- O 8 Study terminated by sponsor
- O 88 Other *(specify reason below)*

  Specify reason: _____[13]

2. Date of disposition: _____/_____/_____ *(mm/dd/yyyy)* [14]

3. Did the investigator review and sign off on the participant's disposition? [15]

- O 1 No
- O 2 Yes

Comments: _____[16]

_____[17]
Initials of person completing the form

_____/_____/_____[18]
Date form completed (mm-dd-yyyy)

To the best of my knowledge, the data collected for the participant are accurate and complete.

Investigator's signature _____

AE ACRIN Adverse Event Form ACRIN Study 6686

ACRIN Study 6686 Case #

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

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

All Adverse Events (AEs) and Serious Adverse Events (SAEs) as defined in the protocol require routine reporting via web entry of the AE CRF. Only one AE is captured per form. For further instructions in completing the form, please refer to the AE completion instructions. Please note that source documentation (ACRIN AE log, ACRIN AE CRF, printed AE web confirmation, or participant's chart) must have the investigator's signature. For AE reporting requirements, please refer to the AE reporting section of the protocol. Contact ACRIN's AE coordinator for any questions.

AE Description _____ [1, 2]

AE Short Name (online look-up) _____ [3]

Grade [4]	**Attribution** [5]	**Expectedness** [6]	**Serious AE?** [42]	**Expedited Report Submitted** [7]	**Action Taken** (mark ☒ all that apply)	**Outcome** [9]	**Date of AE Onset and Resolution** (mm-dd-yyyy); mark ☒ the box "ongoing" if the AE is ongoing at the time of report
O Mild O Moderate O Severe O Life threatening or disabling O Fatal	O Unrelated O Unlikely O Possible O Probable O Definite	O Expected O Unexpected	O No O Yes	O No O Yes	☐ None [43] ☐ Medication therapy [44] ☐ Procedure [45] ☐ Hospitalization [46] ☐ Other [47]	O Recovered O Improved O Ongoing O Death O Unknown	Start date: ____ - ____ - ____ [10] Resolution date: ____ - ____ - ____ [11] ☐ Ongoing [12]

Comments: _____ [37], [38]

Additional AEs to report? [39]
- O No
- O Yes (Please complete an additional AE form)

Was the AE assessed, reviewed and signed by the investigator? [40]
- O No
- O Yes

____-____-____ [41]
Date form completed (mm-dd-yyyy)

_____ [50]
Investigator's initials

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

PR

ACRIN 6686

Phase III Trial of Bevacizumab with Temozaolomide vs. Chemoradiation with Temozaolomide Advanced MRI

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

ACRIN Study 6686 Case #

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

INSTRUCTIONS: In the instance a protocol requirement is not met, record the requested information below. Complete a separate form for each case and for each deviation. Submit this form via the ACRIN web site; retain the form in the case study file.

1. Check the Protocol Event Being Reported: *(select only one)* [1]

- O 1 Inclusion/exclusion criteria not met at time of registration
- O 2 Imaging-related deviation (complete Q1a)
- O 3 Study activity performed without participant consent
- O 5 Visit or follow-up procedures not performed per protocol (specify visit in Q6)
- O 6 Case enrolled under expired IRB approval/FWA
- O 88 Other, specify: _____ [2]

1a. Imaging Deviation: *(Select only one)* [3]

- ☐ 1 Scan not performed according to protocol specific intervals
- ☐ 2 Scan performed at a non-ACRIN qualified institution
- ☐ 3 Scan performed on a non-ACRIN qualified scanner
- ☐ 4 Images lost or unavailable (complete Q1b)
- ☐ 5 Imaging incomplete (complete Q1b)
- ☐ 6 Scan not performed according to protocol specific guidelines (complete Q1b)
- ☐ 7 MultiHance or vasovist contrast agent used
- ☐ 88 Other, specify _____ [4]

1b. Imaging affected *(Select only one)* [5]

- ☐ 1 DCE
- ☐ 2 DSC
- ☐ 88 Other, specify _____ [6]

2. Date the protocol variation occurred: ____ - ____ - **20**____ (mm-dd-yyyy) [7]

3. Date the protocol variation was discovered: ____ - ____ - **20**____ (mm-dd-yyyy) [8]

4. Describe the protocol variation:

_____ [9]

_____ [10]

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

_____ [11]

_____ [12]

6. At what time point did this study deviation occur? [13]

- O Baseline
- O Week 3
- O Week 3 + 1 day
- O Week 10

7. Was variation form signed by investigator? [14]

- O 1 No
- O 2 Yes

_____ [15]

Initials of person responsible for data (RA, study staff)

_____ - _____ - **20**____ (mm-dd-yyyy) [16]

Date Form Completed

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