# ACRIN 6677

## Bevacizumab with Irinotecan
## or
## Bevacizumab with Temozolomide in Recurrent Glioblastoma

# Case Report Form Set

## Imaging Forms for Protocol 0625/6677 — Version Date

### Pre Study Baseline MRI



### Week 2



### Week 8 (Post 2nd cycle of treatment)



### Week 16 (Post 4th cycle of treatment)



### Week 24 (Post 6th cycle of treatment)



### Week 32 (Post 8th cycle of treatment)



### Week 40 (Post 10th cycle of treatment)



### Week 48 (Post 12th cycle of treatment)



### Week 56 (Post 14th cycle of treatment)

## Imaging Forms for Protocol 0625/6677 — Version Date

### Week 64 (Post 16th cycle of treatment)

**M8** Week 64 Standard MRI . . . . . 09-19-07
**V8** Week 64 Advanced MRI . . . . . 11-16-07

### Week 72 (Post 18th cycle of treatment)

**M9** Week 72 Standard MRI . . . . . 09-19-07
**V9** Week 72 Advanced MRI . . . . . 11-16-07

### Week 80 (Post 20nd cycle of treatment)

**MA** Week 80 Standard MRI . . . . . 09-19-07
**VA** Week 80 Advanced MRI . . . . . 11-16-07

### Week 88 (Post 22nd cycle of treatment)

**MB** Week 88 Standard MRI . . . . . 09-19-07
**VB** Week 88 Advanced MRI . . . . . 11-16-07

### Week 96 (Post 24th cycle of treatment)

**MC** Week 96 Standard MRI . . . . . 09-19-07
**VC** Week 96 Advanced MRI . . . . . 11-16-07

### Final (Off-Study Assessment)

**MD** Final Standard MRI . . . . . 09-19-07
**VD** Final Advanced MRI . . . . . 11-16-07

### Interval Scan Advanced MRI

**G1** Advanced MRI Interval Scan . . . . . 03-05-08

### Interval Scan Standard MRI

**B1** Standard MRI Interval Scan . . . . . 03-05-08

### End of Study

**DS** End of Study . . . . . 09-20-07

### Additional Forms

**AE** Adverse Events. . . . . 02-25-08
**PR** Protocol Deviation. . . . . 11-20-07

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:

# Pre-Study Baseline MRI

**M0**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Pre-Study MRI Assessment Form**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## Baseline

**Instructions:** The pre-enrollment imaging and reports are reviewed and the form is completed by the study Radiologist. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as mm/dd/yyyy. All responses are required unless otherwise noted.

## General Imaging Information

**1. Was MRI imaging performed at this visit?** [1]

O No (*complete Q1a then stop and sign form*)
O Yes

**1a.** Reason imaging not performed: *(check only one)* [2]

O Scheduling Problem
O Equipment failure
O Patient refusal
O Medical contraindication
O Injection site complications
O Claustrophobia
O Other, Specify _____ [3]

**1b.** Reader ID |_|_|_|_|_|_|_| [4]

**1c.** Is the image quality sufficient for analysis? [5]

O No
O Yes

**2. Date of MRI:** _____-_____-_____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]

O No
O Yes

**2b.** Was T1 weighted post-contrast imaging performed? [9]

O No
O Yes

**2c.** Was T2 weighted imaging performed? [10]

O No
O Yes

**2d.** Was FLAIR imaging performed? [11]

O No
O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]

O No
O Yes

**3. Patient weight** (measured on day of scan) [16]

|_|_|_|.|_| **kg**

**4. Time of injection (military time)** |_|_|:|_|_| [17]

**5. Contrast administration dose** |_|_|.|_|_| **mmol/kg** [18]

**6. Volume of contrast injection** |_|_|.|_|_| **cc** [20]

**7. Brand of contrast agent injected** *(check only one)* [28]

O Magnevist
O Omniscan
O ProHance
O OptiMark
O Other, specify _____ [29]

**8. Scan start time (military time)** |_|_|:|_|_| [30]

**9. Scan stop time (military time)** |_|_|:|_|_| [31]

**M0**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Pre-Study MRI**
**Assessment Form**

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

ACRIN Study **6677**

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# Baseline

## Pre Enrollment Scans

**10a.** Are lesions present? [32]
O No *(stop and sign form)*
O Yes

**10b.** Series number and slice number used for measurement

**Series Number** ☐☐☐☐☐ [33]

**Slice Number** ☐☐☐☐☐ [34]

**10c.** Largest Cross-sectional Diameter

☐☐☐.☐ mm [35]

**10d.** Largest Perpendicular Diameter

☐☐☐.☐ mm [36]

**10e.** Location Of Primary
*(mark all that apply with a check; ☐ = 1 not marked; ☑ = 2 marked)*

☐ Frontal lobe [37]
☐ Temporal lobe [38]
☐ Parietal lobe [39]
☐ Occipital lobe [40]
☐ Deep (Basal Ganglia/Thalamus) [41]
☐ Cerebellum [42]
☐ Brainstem [43]
☐ Corpus Callosum [44]
☐ Spinal Cord [45]
☐ Other, [46] Specify _____ [47]

**10f.** Lateralization of Tumor [48]
O Right
O Left
O Bilateral

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC and FA:**

**11. Series number and slice number used for measurement**

**Series Number** ☐☐☐☐☐ [51] ☐ **N/A** [83]

**Slice Number** ☐☐☐☐☐ [52] ☐ **N/A** [84]

**12. Center of enhancing mass (in enhancing area):**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ☐☐☐☐☐.☐☐☐☐ [53] ☐ **N/A** [77]

**Mean FA** ☐☐☐☐☐.☐☐☐☐ [54] ☐ **N/A** [78]

**13. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ☐☐☐☐☐.☐☐☐☐ [59] ☐ **N/A** [79]

**Mean FA** ☐☐☐☐☐.☐☐☐☐ [60] ☐ **N/A** [80]

**14. In normal appearing tissue**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ☐☐☐☐☐.☐☐☐☐ [65] ☐ **N/A** [81]

**Mean FA** ☐☐☐☐☐.☐☐☐☐ [66] ☐ **N/A** [82]

**COMMENTS:** _____

_____

_____ [73]

_____ [74]
Signature of person responsible for data

_____-_____-_____ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Signature of person entering data onto the web

**V0**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan Pre-Study Advanced MRI Assessment Form**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## BASELINE

**Instructions:** The advanced MRI imaging and reports are reviewed and the form is completed by the study Radiologist. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as mm/dd/yyyy. All responses are required unless otherwise noted.

## General Imaging Information

**1. Was Advanced MRI imaging performed at this visit?** [1]

O No (*complete Q1a then stop and sign form*)
O Yes

**1a.** Reason imaging not performed: *(check only one)* [2]

O Scheduling Problem
O Equipment failure
O Patient refusal
O Medical contraindication
O Injection site complications
O Claustrophobia
O Other, Specify _____ [3]

**1b.** Reader ID |_|_|_|_|_|_|_|_| [4]

**1c.** Is the image quality sufficient for analysis? [5]

O No
O Yes

**2. Date of advanced MRI:** _____-_____-_____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]

O No
O Yes

**2b.** Was T1 weighted post-contrast imaging performed? [9]

O No
O Yes

**2c.** Was T2 weighted imaging performed? [10]

O No
O Yes

**2d.** Was FLAIR imaging performed? [11]

O No
O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]

O No
O Yes

**2f.** Was DCE imaging performed? [13]

O No
O Yes

**2g.** Was DSC imaging performed? [14]

O No
O Yes

**2h.** Was MRS/MRSI imaging performed? [15]

O No
O Yes

**3. Patient weight** (measured on day of scan) [16]

|_|_|_|.|_|_| **kg**

**4. Time of injection** (military time) |_|_|:|_|_| [17]

**5. Contrast administration dose** |_|_|.|_|_| **mmol/kg** [18]

**6. Rate of injection** |_|_|.|_|_| **cc/sec** [19]

**7. Volume of contrast injection** |_|_|.|_|_| **cc** [20]

**8. Volume of saline injection** |_|_|.|_|_| **cc** [21]

**9. Was second injection performed?** [22]

O No (skip to Q10)
O Yes

**9a. Time of second injection** [23]

(military time) |_|_|:|_|_|

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

**9b.** Contrast administration dose of second injection *(skip if second injection not performed)*

|_|_|.|_|_| mmol/kg [24]

**9c.** Rate of second injection |_|_|.|_|_| cc/sec *(skip if second injection not performed)* [25]

**9d.** Volume of second contrast injection |_|_|.|_|_| cc *(skip if second injection not performed)* [26]

**9e.** Volume of second saline injection |_|_|.|_|_| cc *(skip if second injection not performed)* [27]

**10. Brand of contrast agent injected** *(check only one)* [28]

- O Magnevist
- O Omniscan
- O ProHance
- O OptiMark
- O Other, specify _____ [29]

**11. Scan start time (military time)** |_|_|:|_|_| [30]

**12. Scan stop time (military time)** |_|_|:|_|_| [31]

## Baseline Advanced Imaging Scans

**13a.** Are lesions present? [32]

- O No *(stop and sign form)*
- O Yes

**13b.** Series number and slice number used for measurement

**Series Number** |_|_|_|_|_| [33]

**Slice Number** |_|_|_|_|_| [34]

**13c.** Largest Cross-sectional Diameter

|_|_|_|.|_| mm [35]

**13d.** Largest Perpendicular Diameter

|_|_|_|.|_| mm [36]

# BASELINE

**13e.** Location Of Primary

*(mark all that apply with a check; ☐ = 1 not marked; ☑ = 2 marked)*

- ☐ Frontal lobe [37]
- ☐ Temporal lobe [38]
- ☐ Parietal lobe [39]
- ☐ Occipital lobe [40]
- ☐ Deep (Basal Ganglia/Thalamus) [41]
- ☐ Cerebellum [42]
- ☐ Brainstem [43]
- ☐ Corpus Callosum [44]
- ☐ Spinal Cord [45]
- ☐ Other, [46] Specify _____ [47]

**13f.** Lateralization of Tumor [48]

- O Right
- O Left
- O Bilateral

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC, FA, CBV, Ktrans, Other local permeability, and Choline/NAA ratio:**

**14. Series number and slice number used for measurement**

**Series Number** |_|_|_|_|_| [51] ☐ **N/A** [95]

**Slice Number** |_|_|_|_|_| [52] ☐ **N/A** [96]

**V0**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Pre-Study Advanced MRI Assessment Form**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# BASELINE

**15. Center of enhancing mass (in enhancing area):**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ___.___ [53] ☐ **N/A** [77]

**Mean FA** ___.___ [54] ☐ **N/A** [78]

**Mean CBV** ___.___ [55] ☐ **N/A** [79]

**Mean Ktrans** ___.___ [56] ☐ **N/A** [80]

**Mean Other local permeability**

___.___ [57] ☐ **N/A** [81]

**Mean Choline/NAA ratio**

___.___ [58] ☐ **N/A** [82]

**16. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ___.___ [59] ☐ **N/A** [83]

**Mean FA** ___.___ [60] ☐ **N/A** [84]

**Mean CBV** ___.___ [61] ☐ **N/A** [85]

**Mean Ktrans** ___.___ [62] ☐ **N/A** [86]

**Mean Other local permeability**

___.___ [63] ☐ **N/A** [87]

**Mean Choline/NAA ratio**

___.___ [64] ☐ **N/A** [88]

**17. In normal-appearing tissue**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ___.___ [65] ☐ **N/A** [89]

**Mean FA** ___.___ [66] ☐ **N/A** [90]

**Mean CBV** ___.___ [67] ☐ **N/A** [91]

**Mean Ktrans** ___.___ [68] ☐ **N/A** [92]

**Mean Other local permeability**

___.___ [69] ☐ **N/A** [93]

**Mean Choline/NAA ratio:**

___.___ [70] ☐ **N/A** [94]

**Comments:** _____

_____ [73]

_____ [74]
Radiologist responsible for data

___-___-___ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

# Week 2

**VX**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Week 2**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 2

**Instructions:** The advanced MRI imaging and reports are reviewed and the form is completed by the study Radiologist. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as mm/dd/yyyy. All responses are required unless otherwise noted.

## General Imaging Information

**1. Was Advanced MRI imaging performed at this visit?** [1]
- O No (*complete Q1a then skip to Q18*)
- O Yes

**1a.** Reason imaging not performed: *(check only one)* [2]
- O Scheduling Problem
- O Equipment failure
- O Patient refusal
- O Medical contraindication
- O Injection site complications
- O Claustrophobia
- O Other, Specify _____ [3]

**1b.** Reader ID |_|_|_|_|_|_|_|_| [4]

**1c.** Is the image quality sufficient for analysis? [5]
- O No
- O Yes

**1d.** Was the scanner used for this exam the same as at baseline? [6]
- O No
- O Yes

**2. Date of advanced MRI:** _____-_____-_____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]
- O No
- O Yes

**2b.** Was T-1 weighted post-contrast imaging performed? [9]
- O No
- O Yes

**2c.** Was T2 weighted imaging performed? [10]
- O No
- O Yes

**2d.** Was FLAIR imaging performed? [11]
- O No
- O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]
- O No
- O Yes

**2f.** Was DCE imaging performed? [13]
- O No
- O Yes

**2g.** Was DSC imaging performed? [14]
- O No
- O Yes

**2h.** Was MRS/MRSI imaging performed? [15]
- O No
- O Yes

**3. Patient weight** (measured on day of scan) [16]
|_|_|_|.|_| **kg**

**4. Time of injection** (military time) |_|_|:|_|_| [17]

**5. Contrast administration dose** |_|_|.|_|_| **mmol/kg** [18]

**6. Rate of injection** |_|_|.|_|_| **cc/sec** [19]

**7. Volume of contrast injection** |_|_|.|_|_| **cc** [20]

**8. Volume of saline injection** |_|_|.|_|_| **cc** [21]

**9. Was second injection performed?** [22]
- O No (skip to Q10)
- O Yes

**9a. Time of second injection** [23]
(military time) |_|_|:|_|_|

# WEEK 2

**9b.** Contrast administration dose of second injection *(skip if second injection not performed)*
___.___ mmol/kg [24]

**9c.** Rate of second injection ___.___ cc/sec
*(skip if second injection not performed)* [25]

**9d.** Volume of second contrast injection ___.___ cc
*(skip if second injection not performed)* [26]

**9e.** Volume of second saline injection ___.___ cc
*(skip if second injection not performed)* [27]

**10. Brand of contrast agent injected** *(check only one)* [28]

- O Magnevist
- O Omniscan
- O ProHance
- O OptiMark
- O Other, specify _____ [29]

**11. Scan start time (military time)** __:__ [30]

**12. Scan stop time (military time)** __:__ [31]

## Week 2 Advanced Imaging Scans

**13a.** Are lesions present? [32]

- O No *(complete Q13g then skip to Q18)*
- O Yes

**13b.** Series number and slice number used for measurement

**Series Number** _____ [33]

**Slice Number** _____ [34]

**13c.** Largest Cross-sectional Diameter

___.___ mm [35]

**13d.** Largest Perpendicular Diameter

___.___ mm [36]

**13e.** Location Of Primary (check all that apply)

- ☐ Frontal lobe [37]
- ☐ Temporal lobe [38]
- ☐ Parietal lobe [39]
- ☐ Occipital lobe [40]
- ☐ Deep (Basal Ganglia/Thalamus) [41]
- ☐ Cerebellum [42]
- ☐ Brainstem [43]
- ☐ Corpus Callosum [44]
- ☐ Spinal Cord [45]
- ☐ Other, [46] Specify _____ [47]

**13f.** Lateralization of Tumor [48]

- O Right
- O Left
- O Bilateral

**13g.** Scan Response [49]

- O CR
- O PR
- O Stable
- O Progression
- O Not able to be assessed; specify reason

_____ [50]

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC, FA, CBV, Ktrans, Other local permeability, and Choline/NAA ratio:**

**14. Series number and slice number used for measurement**

**Series Number** _____ [51] ☐ **N/A** [95]

**Slice Number** _____ [52] ☐ **N/A** [96]

**VX**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Week 2**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 2

**15. Center of enhancing mass (in enhancing area):**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ___.___ [53] ☐ **N/A** [77]

**Mean FA** ___.___ [54] ☐ **N/A** [78]

**Mean CBV** ___.___ [55] ☐ **N/A** [79]

**Mean Ktrans** ___.___ [56] ☐ **N/A** [80]

**Mean Other local permeability**

___.___ [57] ☐ **N/A** [81]

**Mean Choline/NAA ratio**

___.___ [58] ☐ **N/A** [82]

**16. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ___.___ [59] ☐ **N/A** [83]

**Mean FA** ___.___ [60] ☐ **N/A** [84]

**Mean CBV** ___.___ [61] ☐ **N/A** [85]

**Mean Ktrans** ___.___ [62] ☐ **N/A** [86]

**Mean Other local permeability**

___.___ [63] ☐ **N/A** [87]

**Mean Choline/NAA ratio**

___.___ [64] ☐ **N/A** [88]

**17. In normal-appearing tissue**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ___.___ [65] ☐ **N/A** [89]

**Mean FA** ___.___ [66] ☐ **N/A** [90]

**Mean CBV** ___.___ [67] ☐ **N/A** [91]

**Mean Ktrans** ___.___ [68] ☐ **N/A** [92]

**Mean Other local permeability**

___.___ [69] ☐ **N/A** [93]

**Mean Choline/NAA ratio:**

___.___ [70] ☐ **N/A** [94]

## Interval Scans

**18. Were any MRI scans performed since last visit excluding today's scan?** [71]

O No
O Yes *(report interval scan results on form G1)*

18a. Number of interval scans performed ___ [72]

**Note: Submit a separate form G1 for each interval scan performed.**

**Comments:** _____

_____ [73]

_____ [74]
Radiologist responsible for data

___-___-___ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

# Week 8
# (Post 2nd cycle of treatment)

**M1**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 8]**
**Post 2nd Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# WEEK 8

**Instructions:** The post 2nd cycle of treatment [8 weeks] imaging and reports are reviewed and the form is completed by the study Radiologist. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as MM/DD/YYYY. All responses are required unless otherwise noted.

## General Imaging Information

**1. Was MRI imaging performed at this visit?** [1]
- O No (*complete Q1a and Q15, then stop and sign form*)
- O Yes

**1a.** Reason imaging not performed: *(check only one)* [2]
- O Scheduling Problem
- O Equipment failure
- O Patient refusal
- O Medical contraindication
- O Injection site complications
- O Claustrophobia
- O Other, Specify _____ [3]

**1b.** Reader ID ☐☐☐☐☐☐☐ [4]

**1c.** Is the image quality sufficient for analysis? [5]
- O No
- O Yes

**1d.** Was the scanner used for this exam the same as at baseline? [6]
- O No
- O Yes

**2. Date of MRI:** ____-____-____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]
- O No
- O Yes

**2b.** Was T1 weighted post-contrast imaging performed? [9]
- O No
- O Yes

**2c.** Was T2 weighted imaging performed? [10]
- O No
- O Yes

**2d.** Was FLAIR imaging performed? [11]
- O No
- O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]
- O No
- O Yes

**3. Patient weight** ☐☐☐.☐ **kg** (measured on day of scan) [16]

**4. Time of injection (military time)** ☐☐:☐☐ [17]

**5. Contrast administration dose** ☐☐.☐☐ **mmol/kg** [18]

**6. Volume of contrast injection** ☐☐.☐☐ **cc** [20]

**7. Brand of contrast agent injected** *(check only one)* [28]
- O Magnevist
- O Omniscan
- O ProHance
- O OptiMark
- O Other, specify _____ [29]

**8. Scan start time (military time)** ☐☐:☐☐ [30]

**9. Scan stop time (military time)** ☐☐:☐☐ [31]

**M1**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 8]**
**Post 2nd Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# WEEK 8

## MRI Assessment [8 Weeks] Post 2nd Cycle of Treatment

**10a.** Are lesions present? [32]

O No (Complete only Q10g and Q15, then sign and date form)
O Yes

**10b.** Series number and slice number used for measurement

**Series Number** ____ [33]

**Slice Number** ____ [34]

**10c.** Largest Cross-sectional Diameter

____.____ mm [35]

**10d.** Largest Perpendicular Diameter

____.____ mm [36]

**10e.** Location Of Primary
*(mark all that apply with a check; ☐ = 1 not marked; ☑ = 2 marked)*

☐ Frontal lobe [37]
☐ Temporal lobe [38]
☐ Parietal lobe [39]
☐ Occipital lobe [40]
☐ Deep (Basal Ganglia/Thalamus) [41]
☐ Cerebellum [42]
☐ Brainstem [43]
☐ Corpus Callosum [44]
☐ Spinal Cord [45]
☐ Other, [46] Specify _____ [47]

**10f.** Lateralization of Tumor [48]

O Right
O Left
O Bilateral

**10g.** Scan Response [49]

O CR
O PR
O Stable
O Progression
O Not able to be assessed; specify reason

_____ [50]

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC and FA:**

**11. Series number and slice number used for measurement**

**Series Number** ____ [51] ☐ **N/A** [83]

**Slice Number** ____ [52] ☐ **N/A** [84]

**12. Center of enhancing mass (in enhancing area):**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [53] ☐ **N/A** [77]

**Mean FA** ____.____ [54] ☐ **N/A** [78]

**13. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [59] ☐ **N/A** [79]

**Mean FA** ____.____ [60] ☐ **N/A** [80]

**14. In normal appearing tissue**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [65] ☐ **N/A** [81]

**Mean FA** ____.____ [66] ☐ **N/A** [82]

## Interval Scans

**15. Were any MRI scans performed since last visit excluding today's scan?** [71]

O No
O Yes (Report interval scan results on form B1)

**15a.** Number of interval scans performed ____ [72]

**Note: Submit a separate form B1 for each interval scan performed.**

**M1**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 8]**
**Post 2nd Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 8

**COMMENTS:** _____

_____

_____

_____ [73]

_____ [74]
Radiologist responsible for data

_____-_____-_____ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

**V1**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Week 8**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 8

**Instructions:** The advanced MRI imaging and reports are reviewed and the form is completed by the study Radiologist. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as mm/dd/yyyy. All responses are required unless otherwise noted.

## General Imaging Information

**1. Was Advanced MRI imaging performed at this visit?** [1]
- O No (*complete Q1a then skip to Q18*)
- O Yes

**1a.** Reason imaging not performed: *(check only one)* [2]
- O Scheduling Problem
- O Equipment failure
- O Patient refusal
- O Medical contraindication
- O Injection site complications
- O Claustrophobia
- O Other, Specify _____ [3]

**1b.** Reader ID |_|_|_|_|_|_|_|_| [4]

**1c.** Is the image quality sufficient for analysis? [5]
- O No
- O Yes

**1d.** Was the scanner used for this exam the same as at baseline? [6]
- O No
- O Yes

**2. Date of advanced MRI:** _____-_____-_____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]
- O No
- O Yes

**2b.** Was T-1 weighted post-contrast imaging performed? [9]
- O No
- O Yes

**2c.** Was T2 weighted imaging performed? [10]
- O No
- O Yes

**2d.** Was FLAIR imaging performed? [11]
- O No
- O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]
- O No
- O Yes

**2f.** Was DCE imaging performed? [13]
- O No
- O Yes

**2g.** Was DSC imaging performed? [14]
- O No
- O Yes

**2h.** Was MRS/MRSI imaging performed? [15]
- O No
- O Yes

**3. Patient weight** (measured on day of scan) [16]
|_|_|_|.|_| **kg**

**4. Time of injection** (military time) |_|_|:|_|_| [17]

**5. Contrast administration dose** |_|_|.|_|_| **mmol/kg** [18]

**6. Rate of injection** |_|_|.|_|_| **cc/sec** [19]

**7. Volume of contrast injection** |_|_|.|_|_| **cc** [20]

**8. Volume of saline injection** |_|_|.|_|_| **cc** [21]

**9. Was second injection performed?** [22]
- O No (skip to Q10)
- O Yes

**9a. Time of second injection** [23]
(military time) |_|_|:|_|_|

# WEEK 8

**9b.** Contrast administration dose of second injection *(skip if second injection not performed)*
___.___ mmol/kg [24]

**9c.** Rate of second injection ___.___ cc/sec
*(skip if second injection not performed)* [25]

**9d.** Volume of second contrast injection ___.___ cc
*(skip if second injection not performed)* [26]

**9e.** Volume of second saline injection ___.___ cc
*(skip if second injection not performed)* [27]

**10. Brand of contrast agent injected** *(check only one)* [28]

- O Magnevist
- O Omniscan
- O ProHance
- O OptiMark
- O Other, specify _____ [29]

**11. Scan start time (military time)** ___:___ [30]

**12. Scan stop time (military time)** ___:___ [31]

## Week 8 Advanced Imaging Scans

**13a.** Are lesions present? [32]

- O No *(complete Q13g then skip to Q18)*
- O Yes

**13b.** Series number and slice number used for measurement

**Series Number** _____ [33]

**Slice Number** _____ [34]

**13c.** Largest Cross-sectional Diameter

___.___ mm [35]

**13d.** Largest Perpendicular Diameter

___.___ mm [36]

**13e.** Location Of Primary (check all that apply)

- ☐ Frontal lobe [37]
- ☐ Temporal lobe [38]
- ☐ Parietal lobe [39]
- ☐ Occipital lobe [40]
- ☐ Deep (Basal Ganglia/Thalamus) [41]
- ☐ Cerebellum [42]
- ☐ Brainstem [43]
- ☐ Corpus Callosum [44]
- ☐ Spinal Cord [45]
- ☐ Other, [46] Specify _____ [47]

**13f.** Lateralization of Tumor [48]

- O Right
- O Left
- O Bilateral

**13g.** Scan Response [49]

- O CR
- O PR
- O Stable
- O Progression
- O Not able to be assessed; specify reason

_____ [50]

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC, FA, CBV, Ktrans, Other local permeability, and Choline/NAA ratio:**

**14. Series number and slice number used for measurement**

**Series Number** _____ [51] ☐ **N/A** [95]

**Slice Number** _____ [52] ☐ **N/A** [96]

**V1**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Week 8**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 8

**15. Center of enhancing mass (in enhancing area):**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [53] ☐ **N/A** [77]

**Mean FA** ____.____ [54] ☐ **N/A** [78]

**Mean CBV** ____.____ [55] ☐ **N/A** [79]

**Mean Ktrans** ____.____ [56] ☐ **N/A** [80]

**Mean Other local permeability**

____.____ [57] ☐ **N/A** [81]

**Mean Choline/NAA ratio**

____.____ [58] ☐ **N/A** [82]

**16. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [59] ☐ **N/A** [83]

**Mean FA** ____.____ [60] ☐ **N/A** [84]

**Mean CBV** ____.____ [61] ☐ **N/A** [85]

**Mean Ktrans** ____.____ [62] ☐ **N/A** [86]

**Mean Other local permeability**

____.____ [63] ☐ **N/A** [87]

**Mean Choline/NAA ratio**

____.____ [64] ☐ **N/A** [88]

**17. In normal-appearing tissue**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [65] ☐ **N/A** [89]

**Mean FA** ____.____ [66] ☐ **N/A** [90]

**Mean CBV** ____.____ [67] ☐ **N/A** [91]

**Mean Ktrans** ____.____ [68] ☐ **N/A** [92]

**Mean Other local permeability**

____.____ [69] ☐ **N/A** [93]

**Mean Choline/NAA ratio:**

____.____ [70] ☐ **N/A** [94]

## Interval Scans

**18. Were any MRI scans performed since last visit excluding today's scan?** [71]

- O No
- O Yes *(report interval scan results on form G1)*

18a. Number of interval scans performed ____ [72]

**Note: Submit a separate form G1 for each interval scan performed.**

**Comments:** _____

_____ [73]

_____ [74]
Radiologist responsible for data

____-____-____ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

# Week 16
# (Post 4th cycle of treatment)

**M2**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 16]**
**Post 4th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 16

**Instructions:** The post 4th cycle of treatment [16 weeks] imaging and reports are reviewed and the form is completed by the study Radiologist. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as MM/DD/YYYY. All responses are required unless otherwise noted.

## General Imaging Information

**1. Was MRI imaging performed at this visit?** [1]
- O No (*complete Q1a and Q15, then stop and sign form*)
- O Yes

**1a.** Reason imaging not performed: *(check only one)* [2]
- O Scheduling Problem
- O Equipment failure
- O Patient refusal
- O Medical contraindication
- O Injection site complications
- O Claustrophobia
- O Other, Specify _____ [3]

**1b.** Reader ID |_|_|_|_|_|_|_| [4]

**1c.** Is the image quality sufficient for analysis? [5]
- O No
- O Yes

**1d.** Was the scanner used for this exam the same as at baseline? [6]
- O No
- O Yes

**2. Date of MRI:** ____-____-____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]
- O No
- O Yes

**2b.** Was T1 weighted post-contrast imaging performed? [9]
- O No
- O Yes

**2c.** Was T2 weighted imaging performed? [10]
- O No
- O Yes

**2d.** Was FLAIR imaging performed? [11]
- O No
- O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]
- O No
- O Yes

**3. Patient weight** |_|_|_|.|_|_| **kg** (measured on day of scan) [16]

**4. Time of injection (military time)** |_|_|:|_|_| [17]

**5. Contrast administration dose** |_|_|.|_|_| **mmol/kg** [18]

**6. Volume of contrast injection** |_|_|.|_|_| **cc** [20]

**7. Brand of contrast agent injected** *(check only one)* [28]
- O Magnevist
- O Omniscan
- O ProHance
- O OptiMark
- O Other, specify _____ [29]

**8. Scan start time (military time)** |_|_|:|_|_| [30]

**9. Scan stop time (military time)** |_|_|:|_|_| [31]

**M2**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 16]**
**Post 4th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# WEEK 16

## MRI Assessment [16 Weeks] Post 4th Cycle of Treatment

**10a.** Are lesions present? [32]
- O No (Complete only Q10g and Q15, then sign and date form)
- O Yes

**10b.** Series number and slice number used for measurement

**Series Number** ☐☐☐☐☐ [33]

**Slice Number** ☐☐☐☐☐ [34]

**10c.** Largest Cross-sectional Diameter

☐☐☐.☐ mm [35]

**10d.** Largest Perpendicular Diameter

☐☐☐.☐ mm [36]

**10e.** Location Of Primary
*(mark all that apply with a check; ☐ = 1 not marked; ☑ = 2 marked)*

- ☐ Frontal lobe [37]
- ☐ Temporal lobe [38]
- ☐ Parietal lobe [39]
- ☐ Occipital lobe [40]
- ☐ Deep (Basal Ganglia/Thalamus) [41]
- ☐ Cerebellum [42]
- ☐ Brainstem [43]
- ☐ Corpus Callosum [44]
- ☐ Spinal Cord [45]
- ☐ Other, [46] Specify _____ [47]

**10f.** Lateralization of Tumor [48]
- O Right
- O Left
- O Bilateral

**10g.** Scan Response [49]
- O CR
- O PR
- O Stable
- O Progression
- O Not able to be assessed; specify reason

_____ [50]

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC and FA:**

**11. Series number and slice number used for measurement**

**Series Number** ☐☐☐☐☐ [51] ☐ **N/A** [83]

**Slice Number** ☐☐☐☐☐ [52] ☐ **N/A** [84]

**12. Center of enhancing mass (in enhancing area):**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ☐☐☐☐☐.☐☐☐☐ [53] ☐ **N/A** [77]

**Mean FA** ☐☐☐☐☐.☐☐☐☐ [54] ☐ **N/A** [78]

**13. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ☐☐☐☐☐.☐☐☐☐ [59] ☐ **N/A** [79]

**Mean FA** ☐☐☐☐☐.☐☐☐☐ [60] ☐ **N/A** [80]

**14. In normal appearing tissue**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ☐☐☐☐☐.☐☐☐☐ [65] ☐ **N/A** [81]

**Mean FA** ☐☐☐☐☐.☐☐☐☐ [66] ☐ **N/A** [82]

## Interval Scans

**15. Were any MRI scans performed since last visit excluding today's scan?** [71]
- O No
- O Yes (Report interval scan results on form B1)

**15a.** Number of interval scans performed ☐☐ [72]

**Note: Submit a separate form B1 for each interval scan performed.**

**M2**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 16]**
**Post 4th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 16

**COMMENTS:** _____

_____

_____

_____ [73]

_____ [74]
Radiologist responsible for data

_____-_____-_____ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

**V2**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Week 16**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 16

**Instructions:** The advanced MRI imaging and reports are reviewed and the form is completed by the study Radiologist. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as mm/dd/yyyy. All responses are required unless otherwise noted.

## General Imaging Information

**1. Was Advanced MRI imaging performed at this visit?** [1]
- O No (*complete Q1a then skip to Q18*)
- O Yes

**1a.** Reason imaging not performed: *(check only one)* [2]
- O Scheduling Problem
- O Equipment failure
- O Patient refusal
- O Medical contraindication
- O Injection site complications
- O Claustrophobia
- O Other, Specify _____ [3]

**1b.** Reader ID |_|_|_|_|_|_|_|_| [4]

**1c.** Is the image quality sufficient for analysis? [5]
- O No
- O Yes

**1d.** Was the scanner used for this exam the same as at baseline? [6]
- O No
- O Yes

**2. Date of advanced MRI:** _____-_____-_____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]
- O No
- O Yes

**2b.** Was T-1 weighted post-contrast imaging performed? [9]
- O No
- O Yes

**2c.** Was T2 weighted imaging performed? [10]
- O No
- O Yes

**2d.** Was FLAIR imaging performed? [11]
- O No
- O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]
- O No
- O Yes

**2f.** Was DCE imaging performed? [13]
- O No
- O Yes

**2g.** Was DSC imaging performed? [14]
- O No
- O Yes

**2h.** Was MRS/MRSI imaging performed? [15]
- O No
- O Yes

**3. Patient weight** (measured on day of scan) [16]
|_|_|_|.|_| **kg**

**4. Time of injection** (military time) |_|_|:|_|_| [17]

**5. Contrast administration dose** |_|_|.|_|_| **mmol/kg** [18]

**6. Rate of injection** |_|_|.|_|_| **cc/sec** [19]

**7. Volume of contrast injection** |_|_|.|_|_| **cc** [20]

**8. Volume of saline injection** |_|_|.|_|_| **cc** [21]

**9. Was second injection performed?** [22]
- O No (skip to Q10)
- O Yes

**9a. Time of second injection** [23]
(military time) |_|_|:|_|_|

# WEEK 16

**9b.** Contrast administration dose of second injection *(skip if second injection not performed)*
___.___ mmol/kg [24]

**9c.** Rate of second injection ___.___ cc/sec
*(skip if second injection not performed)* [25]

**9d.** Volume of second contrast injection ___.___ cc
*(skip if second injection not performed)* [26]

**9e.** Volume of second saline injection ___.___ cc
*(skip if second injection not performed)* [27]

**10. Brand of contrast agent injected** *(check only one)* [28]

- O Magnevist
- O Omniscan
- O ProHance
- O OptiMark
- O Other, specify _____ [29]

**11. Scan start time (military time)** ___:___ [30]

**12. Scan stop time (military time)** ___:___ [31]

## Week 16 Advanced Imaging Scans

**13a.** Are lesions present? [32]

- O No *(complete Q13g then skip to Q18)*
- O Yes

**13b.** Series number and slice number used for measurement

**Series Number** _____ [33]

**Slice Number** _____ [34]

**13c.** Largest Cross-sectional Diameter

___.___ mm [35]

**13d.** Largest Perpendicular Diameter

___.___ mm [36]

**13e.** Location Of Primary (check all that apply)

- ☐ Frontal lobe [37]
- ☐ Temporal lobe [38]
- ☐ Parietal lobe [39]
- ☐ Occipital lobe [40]
- ☐ Deep (Basal Ganglia/Thalamus) [41]
- ☐ Cerebellum [42]
- ☐ Brainstem [43]
- ☐ Corpus Callosum [44]
- ☐ Spinal Cord [45]
- ☐ Other, [46] Specify _____ [47]

**13f.** Lateralization of Tumor [48]

- O Right
- O Left
- O Bilateral

**13g.** Scan Response [49]

- O CR
- O PR
- O Stable
- O Progression
- O Not able to be assessed; specify reason

_____ [50]

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC, FA, CBV, Ktrans, Other local permeability, and Choline/NAA ratio:**

**14. Series number and slice number used for measurement**

**Series Number** _____ [51] ☐ **N/A** [95]

**Slice Number** _____ [52] ☐ **N/A** [96]

**V2**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Week 16**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 16

**15. Center of enhancing mass (in enhancing area):**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [53] ☐ **N/A** [77]

**Mean FA** ____.____ [54] ☐ **N/A** [78]

**Mean CBV** ____.____ [55] ☐ **N/A** [79]

**Mean Ktrans** ____.____ [56] ☐ **N/A** [80]

**Mean Other local permeability**

____.____ [57] ☐ **N/A** [81]

**Mean Choline/NAA ratio**

____.____ [58] ☐ **N/A** [82]

**16. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [59] ☐ **N/A** [83]

**Mean FA** ____.____ [60] ☐ **N/A** [84]

**Mean CBV** ____.____ [61] ☐ **N/A** [85]

**Mean Ktrans** ____.____ [62] ☐ **N/A** [86]

**Mean Other local permeability**

____.____ [63] ☐ **N/A** [87]

**Mean Choline/NAA ratio**

____.____ [64] ☐ **N/A** [88]

**17. In normal-appearing tissue**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [65] ☐ **N/A** [89]

**Mean FA** ____.____ [66] ☐ **N/A** [90]

**Mean CBV** ____.____ [67] ☐ **N/A** [91]

**Mean Ktrans** ____.____ [68] ☐ **N/A** [92]

**Mean Other local permeability**

____.____ [69] ☐ **N/A** [93]

**Mean Choline/NAA ratio:**

____.____ [70] ☐ **N/A** [94]

## Interval Scans

**18. Were any MRI scans performed since last visit excluding today's scan?** [71]

O No
O Yes *(report interval scan results on form G1)*

18a. Number of interval scans performed ____ [72]

**Note: Submit a separate form G1 for each interval scan performed.**

**Comments:** _____

_____ [73]

_____ [74]
Radiologist responsible for data

____-____-____ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

# Week 24
# (Post 6th cycle of treatment)

**M3**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 24]**
**Post 6th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# WEEK 24

**Instructions:** The post 6th cycle of treatment [24 weeks] imaging and reports are reviewed and the form is completed by the study Radiologist. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as MM/DD/YYYY. All responses are required unless otherwise noted.

## General Imaging Information

**1. Was MRI imaging performed at this visit?** [1]
- O No (*complete Q1a and Q15, then stop and sign form*)
- O Yes

**1a.** Reason imaging not performed: *(check only one)* [2]
- O Scheduling Problem
- O Equipment failure
- O Patient refusal
- O Medical contraindication
- O Injection site complications
- O Claustrophobia
- O Other, Specify _____ [3]

**1b.** Reader ID |_|_|_|_|_|_|_| [4]

**1c.** Is the image quality sufficient for analysis? [5]
- O No
- O Yes

**1d.** Was the scanner used for this exam the same as at baseline? [6]
- O No
- O Yes

**2. Date of MRI:** ____-____-____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]
- O No
- O Yes

**2b.** Was T1 weighted post-contrast imaging performed? [9]
- O No
- O Yes

**2c.** Was T2 weighted imaging performed? [10]
- O No
- O Yes

**2d.** Was FLAIR imaging performed? [11]
- O No
- O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]
- O No
- O Yes

**3. Patient weight** |_|_|_|.|_| **kg** (measured on day of scan) [16]

**4. Time of injection (military time)** |_|_|:|_|_| [17]

**5. Contrast administration dose** |_|_|.|_|_| **mmol/kg** [18]

**6. Volume of contrast injection** |_|_|.|_|_| **cc** [20]

**7. Brand of contrast agent injected** *(check only one)* [28]
- O Magnevist
- O Omniscan
- O ProHance
- O OptiMark
- O Other, specify _____ [29]

**8. Scan start time (military time)** |_|_|:|_|_| [30]

**9. Scan stop time (military time)** |_|_|:|_|_| [31]

**M3**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 24]**
**Post 6th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# WEEK 24

## MRI Assessment [24 Weeks] Post 6th Cycle of Treatment

**10a.** Are lesions present? [32]
- O No (Complete only Q10g and Q15, then sign and date form)
- O Yes

**10b.** Series number and slice number used for measurement

**Series Number** ☐☐☐☐☐ [33]

**Slice Number** ☐☐☐☐☐ [34]

**10c.** Largest Cross-sectional Diameter

☐☐☐.☐ mm [35]

**10d.** Largest Perpendicular Diameter

☐☐☐.☐ mm [36]

**10e.** Location Of Primary
*(mark all that apply with a check; ☐ = 1 not marked; ☑ = 2 marked)*

- ☐ Frontal lobe [37]
- ☐ Temporal lobe [38]
- ☐ Parietal lobe [39]
- ☐ Occipital lobe [40]
- ☐ Deep (Basal Ganglia/Thalamus) [41]
- ☐ Cerebellum [42]
- ☐ Brainstem [43]
- ☐ Corpus Callosum [44]
- ☐ Spinal Cord [45]
- ☐ Other, [46] Specify _____ [47]

**10f.** Lateralization of Tumor [48]
- O Right
- O Left
- O Bilateral

**10g.** Scan Response [49]
- O CR
- O PR
- O Stable
- O Progression
- O Not able to be assessed; specify reason

_____ [50]

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC and FA:**

**11. Series number and slice number used for measurement**

**Series Number** ☐☐☐☐☐ [51] ☐ **N/A** [83]

**Slice Number** ☐☐☐☐☐ [52] ☐ **N/A** [84]

**12. Center of enhancing mass (in enhancing area):**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ☐☐☐☐☐.☐☐☐☐ [53] ☐ **N/A** [77]

**Mean FA** ☐☐☐☐☐.☐☐☐☐ [54] ☐ **N/A** [78]

**13. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ☐☐☐☐☐.☐☐☐☐ [59] ☐ **N/A** [79]

**Mean FA** ☐☐☐☐☐.☐☐☐☐ [60] ☐ **N/A** [80]

**14. In normal appearing tissue**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ☐☐☐☐☐.☐☐☐☐ [65] ☐ **N/A** [81]

**Mean FA** ☐☐☐☐☐.☐☐☐☐ [66] ☐ **N/A** [82]

## Interval Scans

**15. Were any MRI scans performed since last visit excluding today's scan?** [71]
- O No
- O Yes (Report interval scan results on form B1)

**15a.** Number of interval scans performed ☐☐ [72]

**Note: Submit a separate form B1 for each interval scan performed.**

**M3**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 24]**
**Post 6th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 24

**COMMENTS:** _____

_____

_____

_____ [73]

_____ [74]
Radiologist responsible for data

_____-_____-_____ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

**V3**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Week 24**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 24

**Instructions:** The advanced MRI imaging and reports are reviewed and the form is completed by the study Radiologist. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as mm/dd/yyyy. All responses are required unless otherwise noted.

## General Imaging Information

**1. Was Advanced MRI imaging performed at this visit?** [1]
- O No (*complete Q1a then skip to Q18*)
- O Yes

**1a.** Reason imaging not performed: *(check only one)* [2]
- O Scheduling Problem
- O Equipment failure
- O Patient refusal
- O Medical contraindication
- O Injection site complications
- O Claustrophobia
- O Other, Specify _____ [3]

**1b.** Reader ID |_|_|_|_|_|_|_|_| [4]

**1c.** Is the image quality sufficient for analysis? [5]
- O No
- O Yes

**1d.** Was the scanner used for this exam the same as at baseline? [6]
- O No
- O Yes

**2. Date of advanced MRI:** _____-_____-_____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]
- O No
- O Yes

**2b.** Was T-1 weighted post-contrast imaging performed? [9]
- O No
- O Yes

**2c.** Was T2 weighted imaging performed? [10]
- O No
- O Yes

**2d.** Was FLAIR imaging performed? [11]
- O No
- O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]
- O No
- O Yes

**2f.** Was DCE imaging performed? [13]
- O No
- O Yes

**2g.** Was DSC imaging performed? [14]
- O No
- O Yes

**2h.** Was MRS/MRSI imaging performed? [15]
- O No
- O Yes

**3. Patient weight** (measured on day of scan) [16]
|_|_|_|.|_| **kg**

**4. Time of injection** (military time) |_|_|:|_|_| [17]

**5. Contrast administration dose** |_|_|.|_|_| **mmol/kg** [18]

**6. Rate of injection** |_|_|.|_|_| **cc/sec** [19]

**7. Volume of contrast injection** |_|_|.|_|_| **cc** [20]

**8. Volume of saline injection** |_|_|.|_|_| **cc** [21]

**9. Was second injection performed?** [22]
- O No (skip to Q10)
- O Yes

**9a. Time of second injection** [23]
(military time) |_|_|:|_|_|

# WEEK 24

**9b.** Contrast administration dose of second injection *(skip if second injection not performed)*
___.___ mmol/kg [24]

**9c.** Rate of second injection ___.___ cc/sec *(skip if second injection not performed)* [25]

**9d.** Volume of second contrast injection ___.___ cc *(skip if second injection not performed)* [26]

**9e.** Volume of second saline injection ___.___ cc *(skip if second injection not performed)* [27]

**10. Brand of contrast agent injected** *(check only one)* [28]

- O Magnevist
- O Omniscan
- O ProHance
- O OptiMark
- O Other, specify _____ [29]

**11. Scan start time (military time)** ___:___ [30]

**12. Scan stop time (military time)** ___:___ [31]

## Week 24 Advanced Imaging Scans

**13a.** Are lesions present? [32]

- O No *(complete Q13g then skip to Q18)*
- O Yes

**13b.** Series number and slice number used for measurement

**Series Number** _____ [33]

**Slice Number** _____ [34]

**13c.** Largest Cross-sectional Diameter

___.___ mm [35]

**13d.** Largest Perpendicular Diameter

___.___ mm [36]

**13e.** Location Of Primary (check all that apply)

- ☐ Frontal lobe [37]
- ☐ Temporal lobe [38]
- ☐ Parietal lobe [39]
- ☐ Occipital lobe [40]
- ☐ Deep (Basal Ganglia/Thalamus) [41]
- ☐ Cerebellum [42]
- ☐ Brainstem [43]
- ☐ Corpus Callosum [44]
- ☐ Spinal Cord [45]
- ☐ Other, [46] Specify _____ [47]

**13f.** Lateralization of Tumor [48]

- O Right
- O Left
- O Bilateral

**13g.** Scan Response [49]

- O CR
- O PR
- O Stable
- O Progression
- O Not able to be assessed; specify reason

_____ [50]

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC, FA, CBV, Ktrans, Other local permeability, and Choline/NAA ratio:**

**14. Series number and slice number used for measurement**

**Series Number** _____ [51] ☐ **N/A** [95]

**Slice Number** _____ [52] ☐ **N/A** [96]

**V3**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Week 24**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 24

**15. Center of enhancing mass (in enhancing area):**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [53] ☐ **N/A** [77]

**Mean FA** ____.____ [54] ☐ **N/A** [78]

**Mean CBV** ____.____ [55] ☐ **N/A** [79]

**Mean Ktrans** ____.____ [56] ☐ **N/A** [80]

**Mean Other local permeability**

____.____ [57] ☐ **N/A** [81]

**Mean Choline/NAA ratio**

____.____ [58] ☐ **N/A** [82]

**16. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [59] ☐ **N/A** [83]

**Mean FA** ____.____ [60] ☐ **N/A** [84]

**Mean CBV** ____.____ [61] ☐ **N/A** [85]

**Mean Ktrans** ____.____ [62] ☐ **N/A** [86]

**Mean Other local permeability**

____.____ [63] ☐ **N/A** [87]

**Mean Choline/NAA ratio**

____.____ [64] ☐ **N/A** [88]

**17. In normal-appearing tissue**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [65] ☐ **N/A** [89]

**Mean FA** ____.____ [66] ☐ **N/A** [90]

**Mean CBV** ____.____ [67] ☐ **N/A** [91]

**Mean Ktrans** ____.____ [68] ☐ **N/A** [92]

**Mean Other local permeability**

____.____ [69] ☐ **N/A** [93]

**Mean Choline/NAA ratio:**

____.____ [70] ☐ **N/A** [94]

## Interval Scans

**18. Were any MRI scans performed since last visit excluding today's scan?** [71]

- O No
- O Yes *(report interval scan results on form G1)*

18a. Number of interval scans performed ____ [72]

**Note: Submit a separate form G1 for each interval scan performed.**

**Comments:** _____

_____ [73]

_____ [74]
Radiologist responsible for data

____-____-____ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

# Week 32
# (Post 8th cycle of treatment)

**M4**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 32]**
**Post 8th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 32

**Instructions:** The post 8th cycle of treatment [32 weeks] imaging and reports are reviewed and the form is completed by the study Radiologist. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as MM/DD/YYYY. All responses are required unless otherwise noted.

## General Imaging Information

**1. Was MRI imaging performed at this visit?** [1]
- O No (*complete Q1a and Q15, then stop and sign form*)
- O Yes

**1a.** Reason imaging not performed: *(check only one)* [2]
- O Scheduling Problem
- O Equipment failure
- O Patient refusal
- O Medical contraindication
- O Injection site complications
- O Claustrophobia
- O Other, Specify _____ [3]

**1b.** Reader ID ☐☐☐☐☐☐☐ [4]

**1c.** Is the image quality sufficient for analysis? [5]
- O No
- O Yes

**1d.** Was the scanner used for this exam the same as at baseline? [6]
- O No
- O Yes

**2. Date of MRI:** ____-____-____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]
- O No
- O Yes

**2b.** Was T1 weighted post-contrast imaging performed? [9]
- O No
- O Yes

**2c.** Was T2 weighted imaging performed? [10]
- O No
- O Yes

**2d.** Was FLAIR imaging performed? [11]
- O No
- O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]
- O No
- O Yes

**3. Patient weight** ☐☐☐.☐ **kg** (measured on day of scan) [16]

**4. Time of injection (military time)** ☐☐:☐☐ [17]

**5. Contrast administration dose** ☐☐.☐☐ **mmol/kg** [18]

**6. Volume of contrast injection** ☐☐.☐☐ **cc** [20]

**7. Brand of contrast agent injected** *(check only one)* [28]
- O Magnevist
- O Omniscan
- O ProHance
- O OptiMark
- O Other, specify _____ [29]

**8. Scan start time (military time)** ☐☐:☐☐ [30]

**9. Scan stop time (military time)** ☐☐:☐☐ [31]

**M4**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 32]**
**Post 8th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# WEEK 32

## MRI Assessment [32 Weeks] Post 8th Cycle of Treatment

**10a.** Are lesions present? [32]
- O No (Complete only Q10g and Q15, then sign and date form)
- O Yes

**10b.** Series number and slice number used for measurement

**Series Number** ☐☐☐☐☐ [33]

**Slice Number** ☐☐☐☐☐ [34]

**10c.** Largest Cross-sectional Diameter

☐☐☐.☐ mm [35]

**10d.** Largest Perpendicular Diameter

☐☐☐.☐ mm [36]

**10e.** Location Of Primary
*(mark all that apply with a check; ☐ = 1 not marked; ☑ = 2 marked)*

- ☐ Frontal lobe [37]
- ☐ Temporal lobe [38]
- ☐ Parietal lobe [39]
- ☐ Occipital lobe [40]
- ☐ Deep (Basal Ganglia/Thalamus) [41]
- ☐ Cerebellum [42]
- ☐ Brainstem [43]
- ☐ Corpus Callosum [44]
- ☐ Spinal Cord [45]
- ☐ Other, [46] Specify _____ [47]

**10f.** Lateralization of Tumor [48]
- O Right
- O Left
- O Bilateral

**10g.** Scan Response [49]
- O CR
- O PR
- O Stable
- O Progression
- O Not able to be assessed; specify reason

_____ [50]

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC and FA:**

**11. Series number and slice number used for measurement**

**Series Number** ☐☐☐☐☐ [51] ☐ **N/A** [83]

**Slice Number** ☐☐☐☐☐ [52] ☐ **N/A** [84]

**12. Center of enhancing mass (in enhancing area):**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ☐☐☐☐☐.☐☐☐☐ [53] ☐ **N/A** [77]

**Mean FA** ☐☐☐☐☐.☐☐☐☐ [54] ☐ **N/A** [78]

**13. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ☐☐☐☐☐.☐☐☐☐ [59] ☐ **N/A** [79]

**Mean FA** ☐☐☐☐☐.☐☐☐☐ [60] ☐ **N/A** [80]

**14. In normal appearing tissue**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ☐☐☐☐☐.☐☐☐☐ [65] ☐ **N/A** [81]

**Mean FA** ☐☐☐☐☐.☐☐☐☐ [66] ☐ **N/A** [82]

## Interval Scans

**15. Were any MRI scans performed since last visit excluding today's scan?** [71]
- O No
- O Yes (Report interval scan results on form B1)

**15a.** Number of interval scans performed ☐☐ [72]

**Note: Submit a separate form B1 for each interval scan performed.**

**M4**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 32]**
**Post 8th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 32

**COMMENTS:** _____

_____

_____

_____ [73]

_____ [74]
Radiologist responsible for data

_____-_____-_____ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

**V4**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Week 32**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# WEEK 32

**Instructions:** The advanced MRI imaging and reports are reviewed and the form is completed by the study Radiologist. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as mm/dd/yyyy. All responses are required unless otherwise noted.

## General Imaging Information

**1. Was Advanced MRI imaging performed at this visit?** [1]
- O No (*complete Q1a then skip to Q18*)
- O Yes

**1a.** Reason imaging not performed: *(check only one)* [2]
- O Scheduling Problem
- O Equipment failure
- O Patient refusal
- O Medical contraindication
- O Injection site complications
- O Claustrophobia
- O Other, Specify _____ [3]

**1b.** Reader ID |_|_|_|_|_|_|_|_| [4]

**1c.** Is the image quality sufficient for analysis? [5]
- O No
- O Yes

**1d.** Was the scanner used for this exam the same as at baseline? [6]
- O No
- O Yes

**2. Date of advanced MRI:** _____-_____-_____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]
- O No
- O Yes

**2b.** Was T-1 weighted post-contrast imaging performed? [9]
- O No
- O Yes

**2c.** Was T2 weighted imaging performed? [10]
- O No
- O Yes

**2d.** Was FLAIR imaging performed? [11]
- O No
- O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]
- O No
- O Yes

**2f.** Was DCE imaging performed? [13]
- O No
- O Yes

**2g.** Was DSC imaging performed? [14]
- O No
- O Yes

**2h.** Was MRS/MRSI imaging performed? [15]
- O No
- O Yes

**3. Patient weight** (measured on day of scan) [16]
|_|_|_|.|_| **kg**

**4. Time of injection** (military time) |_|_|:|_|_| [17]

**5. Contrast administration dose** |_|_|.|_|_| **mmol/kg** [18]

**6. Rate of injection** |_|_|.|_|_| **cc/sec** [19]

**7. Volume of contrast injection** |_|_|.|_|_| **cc** [20]

**8. Volume of saline injection** |_|_|.|_|_| **cc** [21]

**9. Was second injection performed?** [22]
- O No (skip to Q10)
- O Yes

**9a. Time of second injection** [23]
(military time) |_|_|:|_|_|

# WEEK 32

**9b.** Contrast administration dose of second injection *(skip if second injection not performed)*
___.___ mmol/kg [24]

**9c.** Rate of second injection ___.___ cc/sec
*(skip if second injection not performed)* [25]

**9d.** Volume of second contrast injection ___.___ cc
*(skip if second injection not performed)* [26]

**9e.** Volume of second saline injection ___.___ cc
*(skip if second injection not performed)* [27]

**10. Brand of contrast agent injected** *(check only one)* [28]

O Magnevist
O Omniscan
O ProHance
O OptiMark
O Other, specify _____ [29]

**11. Scan start time (military time)** ___:___ [30]

**12. Scan stop time (military time)** ___:___ [31]

## Week 32 Advanced Imaging Scans

**13a.** Are lesions present? [32]

O No *(complete Q13g then skip to Q18)*
O Yes

**13b.** Series number and slice number used for measurement

**Series Number** _____ [33]

**Slice Number** _____ [34]

**13c.** Largest Cross-sectional Diameter

___.___ mm [35]

**13d.** Largest Perpendicular Diameter

___.___ mm [36]

**13e.** Location Of Primary (check all that apply)

☐ Frontal lobe [37]
☐ Temporal lobe [38]
☐ Parietal lobe [39]
☐ Occipital lobe [40]
☐ Deep (Basal Ganglia/Thalamus) [41]
☐ Cerebellum [42]
☐ Brainstem [43]
☐ Corpus Callosum [44]
☐ Spinal Cord [45]
☐ Other, [46] Specify _____ [47]

**13f.** Lateralization of Tumor [48]

O Right
O Left
O Bilateral

**13g.** Scan Response [49]

O CR
O PR
O Stable
O Progression
O Not able to be assessed; specify reason

_____ [50]

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC, FA, CBV, Ktrans, Other local permeability, and Choline/NAA ratio:**

**14. Series number and slice number used for measurement**

**Series Number** _____ [51] ☐ **N/A** [95]

**Slice Number** _____ [52] ☐ **N/A** [96]

**V4**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Week 32**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 32

**15. Center of enhancing mass (in enhancing area):**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [53] ☐ **N/A** [77]

**Mean FA** ____.____ [54] ☐ **N/A** [78]

**Mean CBV** ____.____ [55] ☐ **N/A** [79]

**Mean Ktrans** ____.____ [56] ☐ **N/A** [80]

**Mean Other local permeability**

____.____ [57] ☐ **N/A** [81]

**Mean Choline/NAA ratio**

____.____ [58] ☐ **N/A** [82]

**16. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [59] ☐ **N/A** [83]

**Mean FA** ____.____ [60] ☐ **N/A** [84]

**Mean CBV** ____.____ [61] ☐ **N/A** [85]

**Mean Ktrans** ____.____ [62] ☐ **N/A** [86]

**Mean Other local permeability**

____.____ [63] ☐ **N/A** [87]

**Mean Choline/NAA ratio**

____.____ [64] ☐ **N/A** [88]

**17. In normal-appearing tissue**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [65] ☐ **N/A** [89]

**Mean FA** ____.____ [66] ☐ **N/A** [90]

**Mean CBV** ____.____ [67] ☐ **N/A** [91]

**Mean Ktrans** ____.____ [68] ☐ **N/A** [92]

**Mean Other local permeability**

____.____ [69] ☐ **N/A** [93]

**Mean Choline/NAA ratio:**

____.____ [70] ☐ **N/A** [94]

## Interval Scans

**18. Were any MRI scans performed since last visit excluding today's scan?** [71]

O No
O Yes *(report interval scan results on form G1)*

18a. Number of interval scans performed ____ [72]

**Note: Submit a separate form G1 for each interval scan performed.**

**Comments:** _____

_____ [73]

_____ [74]
Radiologist responsible for data

____-____-____ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

# Week 40
# (Post 10th cycle of treatment)

**M5**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 40]**
**Post 10th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 40

**Instructions:** The post 10th cycle of treatment [40 weeks] imaging and reports are reviewed and the form is completed by the study Radiologist. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as MM/DD/YYYY. All responses are required unless otherwise noted.

## General Imaging Information

**1. Was MRI imaging performed at this visit?** [1]
- O No (*complete Q1a and Q15, then stop and sign form*)
- O Yes

**1a.** Reason imaging not performed: *(check only one)* [2]
- O Scheduling Problem
- O Equipment failure
- O Patient refusal
- O Medical contraindication
- O Injection site complications
- O Claustrophobia
- O Other, Specify _____ [3]

**1b.** Reader ID ☐☐☐☐☐☐☐ [4]

**1c.** Is the image quality sufficient for analysis? [5]
- O No
- O Yes

**1d.** Was the scanner used for this exam the same as at baseline? [6]
- O No
- O Yes

**2. Date of MRI:** ____-____-____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]
- O No
- O Yes

**2b.** Was T1 weighted post-contrast imaging performed? [9]
- O No
- O Yes

**2c.** Was T2 weighted imaging performed? [10]
- O No
- O Yes

**2d.** Was FLAIR imaging performed? [11]
- O No
- O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]
- O No
- O Yes

**3. Patient weight** ☐☐☐.☐ **kg** (measured on day of scan) [16]

**4. Time of injection (military time)** ☐☐:☐☐ [17]

**5. Contrast administration dose** ☐☐.☐☐ **mmol/kg** [18]

**6. Volume of contrast injection** ☐☐.☐☐ **cc** [20]

**7. Brand of contrast agent injected** *(check only one)* [28]
- O Magnevist
- O Omniscan
- O ProHance
- O OptiMark
- O Other, specify _____ [29]

**8. Scan start time (military time)** ☐☐:☐☐ [30]

**9. Scan stop time (military time)** ☐☐:☐☐ [31]

**M5**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 40]**
**Post 10th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# WEEK 40

## MRI Assessment [40 Weeks] Post 10th Cycle of Treatment

**10a.** Are lesions present? [32]
- O No (Complete only Q10g and Q15, then sign and date form)
- O Yes

**10b.** Series number and slice number used for measurement

**Series Number** ____ [33]

**Slice Number** ____ [34]

**10c.** Largest Cross-sectional Diameter

____.____ mm [35]

**10d.** Largest Perpendicular Diameter

____.____ mm [36]

**10e.** Location Of Primary
*(mark all that apply with a check; ☐ = 1 not marked; ☑ = 2 marked)*

- ☐ Frontal lobe [37]
- ☐ Temporal lobe [38]
- ☐ Parietal lobe [39]
- ☐ Occipital lobe [40]
- ☐ Deep (Basal Ganglia/Thalamus) [41]
- ☐ Cerebellum [42]
- ☐ Brainstem [43]
- ☐ Corpus Callosum [44]
- ☐ Spinal Cord [45]
- ☐ Other, [46] Specify _____ [47]

**10f.** Lateralization of Tumor [48]
- O Right
- O Left
- O Bilateral

**10g.** Scan Response [49]
- O CR
- O PR
- O Stable
- O Progression
- O Not able to be assessed; specify reason

_____ [50]

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC and FA:**

**11. Series number and slice number used for measurement**

**Series Number** ____ [51] ☐ **N/A** [83]

**Slice Number** ____ [52] ☐ **N/A** [84]

**12. Center of enhancing mass (in enhancing area):**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [53] ☐ **N/A** [77]

**Mean FA** ____.____ [54] ☐ **N/A** [78]

**13. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [59] ☐ **N/A** [79]

**Mean FA** ____.____ [60] ☐ **N/A** [80]

**14. In normal appearing tissue**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [65] ☐ **N/A** [81]

**Mean FA** ____.____ [66] ☐ **N/A** [82]

## Interval Scans

**15. Were any MRI scans performed since last visit excluding today's scan?** [71]
- O No
- O Yes (Report interval scan results on form B1)

**15a.** Number of interval scans performed ____ [72]

**Note: Submit a separate form B1 for each interval scan performed.**

**M5**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 40]**
**Post 10th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 40

**COMMENTS:** _____

_____

_____

_____ [73]

_____ [74]
Radiologist responsible for data

_____-_____-_____ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

**V5**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Week 40**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 40

**Instructions:** The advanced MRI imaging and reports are reviewed and the form is completed by the study Radiologist. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as mm/dd/yyyy. All responses are required unless otherwise noted.

## General Imaging Information

**1. Was Advanced MRI imaging performed at this visit?** [1]
- O No (*complete Q1a then skip to Q18*)
- O Yes

**1a.** Reason imaging not performed: *(check only one)* [2]
- O Scheduling Problem
- O Equipment failure
- O Patient refusal
- O Medical contraindication
- O Injection site complications
- O Claustrophobia
- O Other, Specify _____ [3]

**1b.** Reader ID |_|_|_|_|_|_|_|_| [4]

**1c.** Is the image quality sufficient for analysis? [5]
- O No
- O Yes

**1d.** Was the scanner used for this exam the same as at baseline? [6]
- O No
- O Yes

**2. Date of advanced MRI:** _____-_____-_____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]
- O No
- O Yes

**2b.** Was T-1 weighted post-contrast imaging performed? [9]
- O No
- O Yes

**2c.** Was T2 weighted imaging performed? [10]
- O No
- O Yes

**2d.** Was FLAIR imaging performed? [11]
- O No
- O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]
- O No
- O Yes

**2f.** Was DCE imaging performed? [13]
- O No
- O Yes

**2g.** Was DSC imaging performed? [14]
- O No
- O Yes

**2h.** Was MRS/MRSI imaging performed? [15]
- O No
- O Yes

**3. Patient weight** (measured on day of scan) [16]
|_|_|_|.|_| **kg**

**4. Time of injection** (military time) |_|_|:|_|_| [17]

**5. Contrast administration dose** |_|_|.|_|_| **mmol/kg** [18]

**6. Rate of injection** |_|_|.|_|_| **cc/sec** [19]

**7. Volume of contrast injection** |_|_|.|_|_| **cc** [20]

**8. Volume of saline injection** |_|_|.|_|_| **cc** [21]

**9. Was second injection performed?** [22]
- O No (skip to Q10)
- O Yes

**9a. Time of second injection** [23]
(military time) |_|_|:|_|_|

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# WEEK 40

**9b.** Contrast administration dose of second injection *(skip if second injection not performed)*
___.___ mmol/kg [24]

**9c.** Rate of second injection ___.___ cc/sec
*(skip if second injection not performed)* [25]

**9d.** Volume of second contrast injection ___.___ cc
*(skip if second injection not performed)* [26]

**9e.** Volume of second saline injection ___.___ cc
*(skip if second injection not performed)* [27]

**10. Brand of contrast agent injected** *(check only one)* [28]

- O Magnevist
- O Omniscan
- O ProHance
- O OptiMark
- O Other, specify _____ [29]

**11. Scan start time (military time)** ___:___ [30]

**12. Scan stop time (military time)** ___:___ [31]

## Week 40 Advanced Imaging Scans

**13a.** Are lesions present? [32]

O No *(complete Q13g then skip to Q18)*
O Yes

**13b.** Series number and slice number used for measurement

**Series Number** _____ [33]

**Slice Number** _____ [34]

**13c.** Largest Cross-sectional Diameter

___.___ mm [35]

**13d.** Largest Perpendicular Diameter

___.___ mm [36]

**13e.** Location Of Primary (check all that apply)

- ☐ Frontal lobe [37]
- ☐ Temporal lobe [38]
- ☐ Parietal lobe [39]
- ☐ Occipital lobe [40]
- ☐ Deep (Basal Ganglia/Thalamus) [41]
- ☐ Cerebellum [42]
- ☐ Brainstem [43]
- ☐ Corpus Callosum [44]
- ☐ Spinal Cord [45]
- ☐ Other, [46] Specify _____ [47]

**13f.** Lateralization of Tumor [48]

O Right
O Left
O Bilateral

**13g.** Scan Response [49]

O CR
O PR
O Stable
O Progression
O Not able to be assessed; specify reason

_____ [50]

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC, FA, CBV, Ktrans, Other local permeability, and Choline/NAA ratio:**

**14. Series number and slice number used for measurement**

**Series Number** _____ [51] ☐ **N/A** [95]

**Slice Number** _____ [52] ☐ **N/A** [96]

**V5**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Week 40**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 40

**15. Center of enhancing mass (in enhancing area):**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ___.___ [53] ☐ **N/A** [77]

**Mean FA** ___.___ [54] ☐ **N/A** [78]

**Mean CBV** ___.___ [55] ☐ **N/A** [79]

**Mean Ktrans** ___.___ [56] ☐ **N/A** [80]

**Mean Other local permeability**

___.___ [57] ☐ **N/A** [81]

**Mean Choline/NAA ratio**

___.___ [58] ☐ **N/A** [82]

**16. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ___.___ [59] ☐ **N/A** [83]

**Mean FA** ___.___ [60] ☐ **N/A** [84]

**Mean CBV** ___.___ [61] ☐ **N/A** [85]

**Mean Ktrans** ___.___ [62] ☐ **N/A** [86]

**Mean Other local permeability**

___.___ [63] ☐ **N/A** [87]

**Mean Choline/NAA ratio**

___.___ [64] ☐ **N/A** [88]

**17. In normal-appearing tissue**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ___.___ [65] ☐ **N/A** [89]

**Mean FA** ___.___ [66] ☐ **N/A** [90]

**Mean CBV** ___.___ [67] ☐ **N/A** [91]

**Mean Ktrans** ___.___ [68] ☐ **N/A** [92]

**Mean Other local permeability**

___.___ [69] ☐ **N/A** [93]

**Mean Choline/NAA ratio:**

___.___ [70] ☐ **N/A** [94]

## Interval Scans

**18. Were any MRI scans performed since last visit excluding today's scan?** [71]

O No
O Yes *(report interval scan results on form G1)*

18a. Number of interval scans performed ___ [72]

**Note: Submit a separate form G1 for each interval scan performed.**

**Comments:** _____

_____ [73]

_____ [74]
Radiologist responsible for data

___-___-___ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

# Week 48
# (Post 12th cycle of treatment)

**M6**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 48]**
**Post 12th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# WEEK 48

**Instructions:** The post 12th cycle of treatment [48 weeks] imaging and reports are reviewed and the form is completed by the study Radiologist. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as MM/DD/YYYY. All responses are required unless otherwise noted.

## General Imaging Information

**1. Was MRI imaging performed at this visit?** [1]
- O No (*complete Q1a and Q15, then stop and sign form*)
- O Yes

**1a.** Reason imaging not performed: *(check only one)* [2]
- O Scheduling Problem
- O Equipment failure
- O Patient refusal
- O Medical contraindication
- O Injection site complications
- O Claustrophobia
- O Other, Specify _____ [3]

**1b.** Reader ID ☐☐☐☐☐☐☐ [4]

**1c.** Is the image quality sufficient for analysis? [5]
- O No
- O Yes

**1d.** Was the scanner used for this exam the same as at baseline? [6]
- O No
- O Yes

**2. Date of MRI:** ____-____-____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]
- O No
- O Yes

**2b.** Was T1 weighted post-contrast imaging performed? [9]
- O No
- O Yes

**2c.** Was T2 weighted imaging performed? [10]
- O No
- O Yes

**2d.** Was FLAIR imaging performed? [11]
- O No
- O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]
- O No
- O Yes

**3. Patient weight** ☐☐☐.☐ **kg** (measured on day of scan) [16]

**4. Time of injection (military time)** ☐☐:☐☐ [17]

**5. Contrast administration dose** ☐☐.☐☐ **mmol/kg** [18]

**6. Volume of contrast injection** ☐☐.☐☐ **cc** [20]

**7. Brand of contrast agent injected** *(check only one)* [28]
- O Magnevist
- O Omniscan
- O ProHance
- O OptiMark
- O Other, specify _____ [29]

**8. Scan start time (military time)** ☐☐:☐☐ [30]

**9. Scan stop time (military time)** ☐☐:☐☐ [31]

**M6**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 48]**
**Post 12th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# WEEK 48

## MRI Assessment [48 Weeks] Post 12th Cycle of Treatment

**10a.** Are lesions present? [32]
- O No (Complete only Q10g and Q15, then sign and date form)
- O Yes

**10b.** Series number and slice number used for measurement

**Series Number** ☐☐☐☐☐ [33]

**Slice Number** ☐☐☐☐☐ [34]

**10c.** Largest Cross-sectional Diameter

☐☐☐.☐ mm [35]

**10d.** Largest Perpendicular Diameter

☐☐☐.☐ mm [36]

**10e.** Location Of Primary
*(mark all that apply with a check; ☐ = 1 not marked; ☑ = 2 marked)*

- ☐ Frontal lobe [37]
- ☐ Temporal lobe [38]
- ☐ Parietal lobe [39]
- ☐ Occipital lobe [40]
- ☐ Deep (Basal Ganglia/Thalamus) [41]
- ☐ Cerebellum [42]
- ☐ Brainstem [43]
- ☐ Corpus Callosum [44]
- ☐ Spinal Cord [45]
- ☐ Other, [46] Specify _____ [47]

**10f.** Lateralization of Tumor [48]
- O Right
- O Left
- O Bilateral

**10g.** Scan Response [49]
- O CR
- O PR
- O Stable
- O Progression
- O Not able to be assessed; specify reason

_____ [50]

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC and FA:**

**11. Series number and slice number used for measurement**

**Series Number** ☐☐☐☐☐ [51] ☐ **N/A** [83]

**Slice Number** ☐☐☐☐☐ [52] ☐ **N/A** [84]

**12. Center of enhancing mass (in enhancing area):**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ☐☐☐☐☐.☐☐☐☐ [53] ☐ **N/A** [77]

**Mean FA** ☐☐☐☐☐.☐☐☐☐ [54] ☐ **N/A** [78]

**13. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ☐☐☐☐☐.☐☐☐☐ [59] ☐ **N/A** [79]

**Mean FA** ☐☐☐☐☐.☐☐☐☐ [60] ☐ **N/A** [80]

**14. In normal appearing tissue**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ☐☐☐☐☐.☐☐☐☐ [65] ☐ **N/A** [81]

**Mean FA** ☐☐☐☐☐.☐☐☐☐ [66] ☐ **N/A** [82]

## Interval Scans

**15. Were any MRI scans performed since last visit excluding today's scan?** [71]
- O No
- O Yes (Report interval scan results on form B1)

**15a.** Number of interval scans performed ☐☐ [72]

**Note: Submit a separate form B1 for each interval scan performed.**

**M6**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 48]**
**Post 12th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 48

**COMMENTS:** _____

_____

_____

_____ [73]

_____ [74]
Radiologist responsible for data

_____-_____-_____ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

**V6**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Week 48**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# WEEK 48

**Instructions:** The advanced MRI imaging and reports are reviewed and the form is completed by the study Radiologist. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as mm/dd/yyyy. All responses are required unless otherwise noted.

## General Imaging Information

**1. Was Advanced MRI imaging performed at this visit?** [1]
- O No (*complete Q1a then skip to Q18*)
- O Yes

**1a.** Reason imaging not performed: *(check only one)* [2]
- O Scheduling Problem
- O Equipment failure
- O Patient refusal
- O Medical contraindication
- O Injection site complications
- O Claustrophobia
- O Other, Specify _____ [3]

**1b.** Reader ID |_|_|_|_|_|_|_|_| [4]

**1c.** Is the image quality sufficient for analysis? [5]
- O No
- O Yes

**1d.** Was the scanner used for this exam the same as at baseline? [6]
- O No
- O Yes

**2. Date of advanced MRI:** _____-_____-_____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]
- O No
- O Yes

**2b.** Was T-1 weighted post-contrast imaging performed? [9]
- O No
- O Yes

**2c.** Was T2 weighted imaging performed? [10]
- O No
- O Yes

**2d.** Was FLAIR imaging performed? [11]
- O No
- O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]
- O No
- O Yes

**2f.** Was DCE imaging performed? [13]
- O No
- O Yes

**2g.** Was DSC imaging performed? [14]
- O No
- O Yes

**2h.** Was MRS/MRSI imaging performed? [15]
- O No
- O Yes

**3. Patient weight** (measured on day of scan) [16]
|_|_|_|.|_| **kg**

**4. Time of injection** (military time) |_|_|:|_|_| [17]

**5. Contrast administration dose** |_|_|.|_|_| **mmol/kg** [18]

**6. Rate of injection** |_|_|.|_|_| **cc/sec** [19]

**7. Volume of contrast injection** |_|_|.|_|_| **cc** [20]

**8. Volume of saline injection** |_|_|.|_|_| **cc** [21]

**9. Was second injection performed?** [22]
- O No (skip to Q10)
- O Yes

**9a. Time of second injection** [23]
(military time) |_|_|:|_|_|

# WEEK 48

**9b.** Contrast administration dose of second injection *(skip if second injection not performed)*
___.___ mmol/kg [24]

**9c.** Rate of second injection ___.___ cc/sec
*(skip if second injection not performed)* [25]

**9d.** Volume of second contrast injection ___.___ cc
*(skip if second injection not performed)* [26]

**9e.** Volume of second saline injection ___.___ cc
*(skip if second injection not performed)* [27]

**10. Brand of contrast agent injected** *(check only one)* [28]

O Magnevist
O Omniscan
O ProHance
O OptiMark
O Other, specify _____ [29]

**11. Scan start time (military time)** ___:___ [30]

**12. Scan stop time (military time)** ___:___ [31]

## Week 48 Advanced Imaging Scans

**13a.** Are lesions present? [32]

O No *(complete Q13g then skip to Q18)*
O Yes

**13b.** Series number and slice number used for measurement

**Series Number** _____ [33]

**Slice Number** _____ [34]

**13c.** Largest Cross-sectional Diameter

___.___ mm [35]

**13d.** Largest Perpendicular Diameter

___.___ mm [36]

**13e.** Location Of Primary (check all that apply)

☐ Frontal lobe [37]
☐ Temporal lobe [38]
☐ Parietal lobe [39]
☐ Occipital lobe [40]
☐ Deep (Basal Ganglia/Thalamus) [41]
☐ Cerebellum [42]
☐ Brainstem [43]
☐ Corpus Callosum [44]
☐ Spinal Cord [45]
☐ Other, [46] Specify _____ [47]

**13f.** Lateralization of Tumor [48]

O Right
O Left
O Bilateral

**13g.** Scan Response [49]

O CR
O PR
O Stable
O Progression
O Not able to be assessed; specify reason

_____ [50]

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC, FA, CBV, Ktrans, Other local permeability, and Choline/NAA ratio:**

**14. Series number and slice number used for measurement**

**Series Number** _____ [51] ☐ **N/A** [95]

**Slice Number** _____ [52] ☐ **N/A** [96]

**V6**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Week 48**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 48

**15. Center of enhancing mass (in enhancing area):**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [53] ☐ **N/A** [77]

**Mean FA** ____.____ [54] ☐ **N/A** [78]

**Mean CBV** ____.____ [55] ☐ **N/A** [79]

**Mean Ktrans** ____.____ [56] ☐ **N/A** [80]

**Mean Other local permeability**

____.____ [57] ☐ **N/A** [81]

**Mean Choline/NAA ratio**

____.____ [58] ☐ **N/A** [82]

**16. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [59] ☐ **N/A** [83]

**Mean FA** ____.____ [60] ☐ **N/A** [84]

**Mean CBV** ____.____ [61] ☐ **N/A** [85]

**Mean Ktrans** ____.____ [62] ☐ **N/A** [86]

**Mean Other local permeability**

____.____ [63] ☐ **N/A** [87]

**Mean Choline/NAA ratio**

____.____ [64] ☐ **N/A** [88]

**17. In normal-appearing tissue**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [65] ☐ **N/A** [89]

**Mean FA** ____.____ [66] ☐ **N/A** [90]

**Mean CBV** ____.____ [67] ☐ **N/A** [91]

**Mean Ktrans** ____.____ [68] ☐ **N/A** [92]

**Mean Other local permeability**

____.____ [69] ☐ **N/A** [93]

**Mean Choline/NAA ratio:**

____.____ [70] ☐ **N/A** [94]

## Interval Scans

**18. Were any MRI scans performed since last visit excluding today's scan?** [71]

- O No
- O Yes *(report interval scan results on form G1)*

18a. Number of interval scans performed ____ [72]

**Note: Submit a separate form G1 for each interval scan performed.**

**Comments:** _____

_____ [73]

_____ [74]
Radiologist responsible for data

____-____-____ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

# Week 56
# (Post 14th cycle of treatment)

**M7**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 56]**
**Post 14th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 56

**Instructions:** The post 14th cycle of treatment [56 weeks] imaging and reports are reviewed and the form is completed by the study Radiologist. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as MM/DD/YYYY. All responses are required unless otherwise noted.

## General Imaging Information

**1. Was MRI imaging performed at this visit?** [1]
- O No (*complete Q1a and Q15, then stop and sign form*)
- O Yes

**1a.** Reason imaging not performed: *(check only one)* [2]
- O Scheduling Problem
- O Equipment failure
- O Patient refusal
- O Medical contraindication
- O Injection site complications
- O Claustrophobia
- O Other, Specify _____ [3]

**1b.** Reader ID |_|_|_|_|_|_|_| [4]

**1c.** Is the image quality sufficient for analysis? [5]
- O No
- O Yes

**1d.** Was the scanner used for this exam the same as at baseline? [6]
- O No
- O Yes

**2. Date of MRI:** ____-____-____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]
- O No
- O Yes

**2b.** Was T1 weighted post-contrast imaging performed? [9]
- O No
- O Yes

**2c.** Was T2 weighted imaging performed? [10]
- O No
- O Yes

**2d.** Was FLAIR imaging performed? [11]
- O No
- O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]
- O No
- O Yes

**3. Patient weight** |_|_|_|.|_|_| **kg** (measured on day of scan) [16]

**4. Time of injection (military time)** |_|_|:|_|_| [17]

**5. Contrast administration dose** |_|_|.|_|_| **mmol/kg** [18]

**6. Volume of contrast injection** |_|_|.|_|_| **cc** [20]

**7. Brand of contrast agent injected** *(check only one)* [28]
- O Magnevist
- O Omniscan
- O ProHance
- O OptiMark
- O Other, specify _____ [29]

**8. Scan start time (military time)** |_|_|:|_|_| [30]

**9. Scan stop time (military time)** |_|_|:|_|_| [31]

**M7**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 56]**
**Post 14th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# WEEK 56

## MRI Assessment [56 Weeks] Post 14th Cycle of Treatment

**10a.** Are lesions present? [32]

O No (Complete only Q10g and Q15, then sign and date form)
O Yes

**10b.** Series number and slice number used for measurement

**Series Number** ____ [33]

**Slice Number** ____ [34]

**10c.** Largest Cross-sectional Diameter

____.____ mm [35]

**10d.** Largest Perpendicular Diameter

____.____ mm [36]

**10e.** Location Of Primary
*(mark all that apply with a check; ☐ = 1 not marked; ☑ = 2 marked)*

☐ Frontal lobe [37]
☐ Temporal lobe [38]
☐ Parietal lobe [39]
☐ Occipital lobe [40]
☐ Deep (Basal Ganglia/Thalamus) [41]
☐ Cerebellum [42]
☐ Brainstem [43]
☐ Corpus Callosum [44]
☐ Spinal Cord [45]
☐ Other, [46] Specify _____ [47]

**10f.** Lateralization of Tumor [48]

O Right
O Left
O Bilateral

**10g.** Scan Response [49]

O CR
O PR
O Stable
O Progression
O Not able to be assessed; specify reason

_____ [50]

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC and FA:**

**11. Series number and slice number used for measurement**

**Series Number** ____ [51] ☐ **N/A** [83]

**Slice Number** ____ [52] ☐ **N/A** [84]

**12. Center of enhancing mass (in enhancing area):**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [53] ☐ **N/A** [77]

**Mean FA** ____.____ [54] ☐ **N/A** [78]

**13. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [59] ☐ **N/A** [79]

**Mean FA** ____.____ [60] ☐ **N/A** [80]

**14. In normal appearing tissue**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [65] ☐ **N/A** [81]

**Mean FA** ____.____ [66] ☐ **N/A** [82]

## Interval Scans

**15. Were any MRI scans performed since last visit excluding today's scan?** [71]

O No
O Yes (Report interval scan results on form B1)

**15a.** Number of interval scans performed ____ [72]

**Note: Submit a separate form B1 for each interval scan performed.**

**M7**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 56]**
**Post 14th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 56

**COMMENTS:** _____

_____

_____

_____ [73]

_____ [74]
Radiologist responsible for data

_____-_____-_____ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

**V7**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Week 56**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 56

**Instructions:** The advanced MRI imaging and reports are reviewed and the form is completed by the study Radiologist. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as mm/dd/yyyy. All responses are required unless otherwise noted.

## General Imaging Information

**1. Was Advanced MRI imaging performed at this visit?** [1]
- O No (*complete Q1a then skip to Q18*)
- O Yes

**1a.** Reason imaging not performed: *(check only one)* [2]
- O Scheduling Problem
- O Equipment failure
- O Patient refusal
- O Medical contraindication
- O Injection site complications
- O Claustrophobia
- O Other, Specify _____ [3]

**1b.** Reader ID |_|_|_|_|_|_|_|_| [4]

**1c.** Is the image quality sufficient for analysis? [5]
- O No
- O Yes

**1d.** Was the scanner used for this exam the same as at baseline? [6]
- O No
- O Yes

**2. Date of advanced MRI:** _____-_____-_____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]
- O No
- O Yes

**2b.** Was T-1 weighted post-contrast imaging performed? [9]
- O No
- O Yes

**2c.** Was T2 weighted imaging performed? [10]
- O No
- O Yes

**2d.** Was FLAIR imaging performed? [11]
- O No
- O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]
- O No
- O Yes

**2f.** Was DCE imaging performed? [13]
- O No
- O Yes

**2g.** Was DSC imaging performed? [14]
- O No
- O Yes

**2h.** Was MRS/MRSI imaging performed? [15]
- O No
- O Yes

**3. Patient weight** (measured on day of scan) [16]
|_|_|_|.|_| **kg**

**4. Time of injection** (military time) |_|_|:|_|_| [17]

**5. Contrast administration dose** |_|_|.|_|_| **mmol/kg** [18]

**6. Rate of injection** |_|_|.|_|_| **cc/sec** [19]

**7. Volume of contrast injection** |_|_|.|_|_| **cc** [20]

**8. Volume of saline injection** |_|_|.|_|_| **cc** [21]

**9. Was second injection performed?** [22]
- O No (skip to Q10)
- O Yes

**9a. Time of second injection** [23]
(military time) |_|_|:|_|_|

# WEEK 56

**9b.** Contrast administration dose of second injection *(skip if second injection not performed)*
__.__ mmol/kg [24]

**9c.** Rate of second injection __.__ cc/sec
*(skip if second injection not performed)* [25]

**9d.** Volume of second contrast injection __.__ cc
*(skip if second injection not performed)* [26]

**9e.** Volume of second saline injection __.__ cc
*(skip if second injection not performed)* [27]

**10. Brand of contrast agent injected** *(check only one)* [28]

- O Magnevist
- O Omniscan
- O ProHance
- O OptiMark
- O Other, specify _____ [29]

**11. Scan start time (military time)** __:__ [30]

**12. Scan stop time (military time)** __:__ [31]

## Week 56 Advanced Imaging Scans

**13a.** Are lesions present? [32]

- O No *(complete Q13g then skip to Q18)*
- O Yes

**13b.** Series number and slice number used for measurement

**Series Number** _____ [33]

**Slice Number** _____ [34]

**13c.** Largest Cross-sectional Diameter

__.__ mm [35]

**13d.** Largest Perpendicular Diameter

__.__ mm [36]

**13e.** Location Of Primary (check all that apply)

- ☐ Frontal lobe [37]
- ☐ Temporal lobe [38]
- ☐ Parietal lobe [39]
- ☐ Occipital lobe [40]
- ☐ Deep (Basal Ganglia/Thalamus) [41]
- ☐ Cerebellum [42]
- ☐ Brainstem [43]
- ☐ Corpus Callosum [44]
- ☐ Spinal Cord [45]
- ☐ Other, [46] Specify _____ [47]

**13f.** Lateralization of Tumor [48]

- O Right
- O Left
- O Bilateral

**13g.** Scan Response [49]

- O CR
- O PR
- O Stable
- O Progression
- O Not able to be assessed; specify reason

_____ [50]

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC, FA, CBV, Ktrans, Other local permeability, and Choline/NAA ratio:**

**14. Series number and slice number used for measurement**

**Series Number** _____ [51] ☐ **N/A** [95]

**Slice Number** _____ [52] ☐ **N/A** [96]

**V7**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Week 56**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 56

**15. Center of enhancing mass (in enhancing area):**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [53] ☐ **N/A** [77]

**Mean FA** ____.____ [54] ☐ **N/A** [78]

**Mean CBV** ____.____ [55] ☐ **N/A** [79]

**Mean Ktrans** ____.____ [56] ☐ **N/A** [80]

**Mean Other local permeability**

____.____ [57] ☐ **N/A** [81]

**Mean Choline/NAA ratio**

____.____ [58] ☐ **N/A** [82]

**16. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [59] ☐ **N/A** [83]

**Mean FA** ____.____ [60] ☐ **N/A** [84]

**Mean CBV** ____.____ [61] ☐ **N/A** [85]

**Mean Ktrans** ____.____ [62] ☐ **N/A** [86]

**Mean Other local permeability**

____.____ [63] ☐ **N/A** [87]

**Mean Choline/NAA ratio**

____.____ [64] ☐ **N/A** [88]

**17. In normal-appearing tissue**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [65] ☐ **N/A** [89]

**Mean FA** ____.____ [66] ☐ **N/A** [90]

**Mean CBV** ____.____ [67] ☐ **N/A** [91]

**Mean Ktrans** ____.____ [68] ☐ **N/A** [92]

**Mean Other local permeability**

____.____ [69] ☐ **N/A** [93]

**Mean Choline/NAA ratio:**

____.____ [70] ☐ **N/A** [94]

## Interval Scans

**18. Were any MRI scans performed since last visit excluding today's scan?** [71]

- O No
- O Yes *(report interval scan results on form G1)*

18a. Number of interval scans performed ____ [72]

**Note: Submit a separate form G1 for each interval scan performed.**

**Comments:** _____

_____ [73]

_____ [74]
Radiologist responsible for data

____-____-____ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

# Week 64
# (Post 16th cycle of treatment)

**M8**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 64]**
**Post 16th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 64

**Instructions:** The post 16th cycle of treatment [64 weeks] imaging and reports are reviewed and the form is completed by the study Radiologist. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as MM/DD/YYYY. All responses are required unless otherwise noted.

## General Imaging Information

**1. Was MRI imaging performed at this visit?** [1]

O No (*complete Q1a and Q15, then stop and sign form*)
O Yes

**1a.** Reason imaging not performed: *(check only one)* [2]

O Scheduling Problem
O Equipment failure
O Patient refusal
O Medical contraindication
O Injection site complications
O Claustrophobia
O Other, Specify _____ [3]

**1b.** Reader ID ☐☐☐☐☐☐☐ [4]

**1c.** Is the image quality sufficient for analysis? [5]

O No
O Yes

**1d.** Was the scanner used for this exam the same as at baseline? [6]

O No
O Yes

**2. Date of MRI:** ____-____-____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]

O No
O Yes

**2b.** Was T1 weighted post-contrast imaging performed? [9]

O No
O Yes

**2c.** Was T2 weighted imaging performed? [10]

O No
O Yes

**2d.** Was FLAIR imaging performed? [11]

O No
O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]

O No
O Yes

**3. Patient weight** ☐☐☐.☐ **kg** (measured on day of scan) [16]

**4. Time of injection (military time)** ☐☐:☐☐ [17]

**5. Contrast administration dose** ☐☐.☐☐ **mmol/kg** [18]

**6. Volume of contrast injection** ☐☐.☐☐ **cc** [20]

**7. Brand of contrast agent injected** *(check only one)* [28]

O Magnevist
O Omniscan
O ProHance
O OptiMark
O Other, specify _____ [29]

**8. Scan start time (military time)** ☐☐:☐☐ [30]

**9. Scan stop time (military time)** ☐☐:☐☐ [31]

**M8**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 64]**
**Post 16th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# WEEK 64

## MRI Assessment [64 Weeks] Post 16th Cycle of Treatment

**10a.** Are lesions present? [32]
- O No (Complete only Q10g and Q15, then sign and date form)
- O Yes

**10b.** Series number and slice number used for measurement

**Series Number** ☐☐☐☐☐ [33]

**Slice Number** ☐☐☐☐☐ [34]

**10c.** Largest Cross-sectional Diameter

☐☐☐.☐ mm [35]

**10d.** Largest Perpendicular Diameter

☐☐☐.☐ mm [36]

**10e.** Location Of Primary
*(mark all that apply with a check; ☐ = 1 not marked; ☑ = 2 marked)*

- ☐ Frontal lobe [37]
- ☐ Temporal lobe [38]
- ☐ Parietal lobe [39]
- ☐ Occipital lobe [40]
- ☐ Deep (Basal Ganglia/Thalamus) [41]
- ☐ Cerebellum [42]
- ☐ Brainstem [43]
- ☐ Corpus Callosum [44]
- ☐ Spinal Cord [45]
- ☐ Other, [46] Specify _____ [47]

**10f.** Lateralization of Tumor [48]
- O Right
- O Left
- O Bilateral

**10g.** Scan Response [49]
- O CR
- O PR
- O Stable
- O Progression
- O Not able to be assessed; specify reason

_____ [50]

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC and FA:**

**11. Series number and slice number used for measurement**

**Series Number** ☐☐☐☐☐ [51] ☐ **N/A** [83]

**Slice Number** ☐☐☐☐☐ [52] ☐ **N/A** [84]

**12. Center of enhancing mass (in enhancing area):**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ☐☐☐☐☐.☐☐☐☐ [53] ☐ **N/A** [77]

**Mean FA** ☐☐☐☐☐.☐☐☐☐ [54] ☐ **N/A** [78]

**13. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ☐☐☐☐☐.☐☐☐☐ [59] ☐ **N/A** [79]

**Mean FA** ☐☐☐☐☐.☐☐☐☐ [60] ☐ **N/A** [80]

**14. In normal appearing tissue**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ☐☐☐☐☐.☐☐☐☐ [65] ☐ **N/A** [81]

**Mean FA** ☐☐☐☐☐.☐☐☐☐ [66] ☐ **N/A** [82]

## Interval Scans

**15. Were any MRI scans performed since last visit excluding today's scan?** [71]
- O No
- O Yes (Report interval scan results on form B1)

**15a.** Number of interval scans performed ☐☐ [72]

**Note: Submit a separate form B1 for each interval scan performed.**

**M8**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 64]**
**Post 16th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 64

**COMMENTS:** _____

_____

_____

_____ [73]

_____ [74]
Radiologist responsible for data

_____-_____-_____ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

**V8**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Week 64**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# WEEK 64

**Instructions:** The advanced MRI imaging and reports are reviewed and the form is completed by the study Radiologist. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as mm/dd/yyyy. All responses are required unless otherwise noted.

## General Imaging Information

**1. Was Advanced MRI imaging performed at this visit?** [1]
- O No (*complete Q1a then skip to Q18*)
- O Yes

**1a.** Reason imaging not performed: *(check only one)* [2]
- O Scheduling Problem
- O Equipment failure
- O Patient refusal
- O Medical contraindication
- O Injection site complications
- O Claustrophobia
- O Other, Specify _____ [3]

**1b.** Reader ID |_|_|_|_|_|_|_|_| [4]

**1c.** Is the image quality sufficient for analysis? [5]
- O No
- O Yes

**1d.** Was the scanner used for this exam the same as at baseline? [6]
- O No
- O Yes

**2. Date of advanced MRI:** _____-_____-_____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]
- O No
- O Yes

**2b.** Was T-1 weighted post-contrast imaging performed? [9]
- O No
- O Yes

**2c.** Was T2 weighted imaging performed? [10]
- O No
- O Yes

**2d.** Was FLAIR imaging performed? [11]
- O No
- O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]
- O No
- O Yes

**2f.** Was DCE imaging performed? [13]
- O No
- O Yes

**2g.** Was DSC imaging performed? [14]
- O No
- O Yes

**2h.** Was MRS/MRSI imaging performed? [15]
- O No
- O Yes

**3. Patient weight** (measured on day of scan) [16]
|_|_|_|.|_| **kg**

**4. Time of injection** (military time) |_|_|:|_|_| [17]

**5. Contrast administration dose** |_|_|.|_|_| **mmol/kg** [18]

**6. Rate of injection** |_|_|.|_|_| **cc/sec** [19]

**7. Volume of contrast injection** |_|_|.|_|_| **cc** [20]

**8. Volume of saline injection** |_|_|.|_|_| **cc** [21]

**9. Was second injection performed?** [22]
- O No (skip to Q10)
- O Yes

**9a. Time of second injection** [23]
(military time) |_|_|:|_|_|

# WEEK 64

**9b.** Contrast administration dose of second injection *(skip if second injection not performed)*
___.___ mmol/kg [24]

**9c.** Rate of second injection ___.___ cc/sec
*(skip if second injection not performed)* [25]

**9d.** Volume of second contrast injection ___.___ cc
*(skip if second injection not performed)* [26]

**9e.** Volume of second saline injection ___.___ cc
*(skip if second injection not performed)* [27]

**10. Brand of contrast agent injected** *(check only one)* [28]

O Magnevist
O Omniscan
O ProHance
O OptiMark
O Other, specify _____ [29]

**11. Scan start time (military time)** __:__ [30]

**12. Scan stop time (military time)** __:__ [31]

## Week 64 Advanced Imaging Scans

**13a.** Are lesions present? [32]

O No *(complete Q13g then skip to Q18)*
O Yes

**13b.** Series number and slice number used for measurement

**Series Number** _____ [33]

**Slice Number** _____ [34]

**13c.** Largest Cross-sectional Diameter

___.___ mm [35]

**13d.** Largest Perpendicular Diameter

___.___ mm [36]

**13e.** Location Of Primary (check all that apply)

☐ Frontal lobe [37]
☐ Temporal lobe [38]
☐ Parietal lobe [39]
☐ Occipital lobe [40]
☐ Deep (Basal Ganglia/Thalamus) [41]
☐ Cerebellum [42]
☐ Brainstem [43]
☐ Corpus Callosum [44]
☐ Spinal Cord [45]
☐ Other, [46] Specify _____ [47]

**13f.** Lateralization of Tumor [48]

O Right
O Left
O Bilateral

**13g.** Scan Response [49]

O CR
O PR
O Stable
O Progression
O Not able to be assessed; specify reason

_____ [50]

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC, FA, CBV, Ktrans, Other local permeability, and Choline/NAA ratio:**

**14. Series number and slice number used for measurement**

**Series Number** _____ [51] ☐ **N/A** [95]

**Slice Number** _____ [52] ☐ **N/A** [96]

**V8**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Week 64**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 64

**15. Center of enhancing mass (in enhancing area):**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ___.___ [53] ☐ **N/A** [77]

**Mean FA** ___.___ [54] ☐ **N/A** [78]

**Mean CBV** ___.___ [55] ☐ **N/A** [79]

**Mean Ktrans** ___.___ [56] ☐ **N/A** [80]

**Mean Other local permeability**

___.___ [57] ☐ **N/A** [81]

**Mean Choline/NAA ratio**

___.___ [58] ☐ **N/A** [82]

**16. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ___.___ [59] ☐ **N/A** [83]

**Mean FA** ___.___ [60] ☐ **N/A** [84]

**Mean CBV** ___.___ [61] ☐ **N/A** [85]

**Mean Ktrans** ___.___ [62] ☐ **N/A** [86]

**Mean Other local permeability**

___.___ [63] ☐ **N/A** [87]

**Mean Choline/NAA ratio**

___.___ [64] ☐ **N/A** [88]

**17. In normal-appearing tissue**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ___.___ [65] ☐ **N/A** [89]

**Mean FA** ___.___ [66] ☐ **N/A** [90]

**Mean CBV** ___.___ [67] ☐ **N/A** [91]

**Mean Ktrans** ___.___ [68] ☐ **N/A** [92]

**Mean Other local permeability**

___.___ [69] ☐ **N/A** [93]

**Mean Choline/NAA ratio:**

___.___ [70] ☐ **N/A** [94]

## Interval Scans

**18. Were any MRI scans performed since last visit excluding today's scan?** [71]

- O No
- O Yes *(report interval scan results on form G1)*

18a. Number of interval scans performed ___ [72]

**Note: Submit a separate form G1 for each interval scan performed.**

**Comments:** _____

_____ [73]

_____ [74]
Radiologist responsible for data

_____-_____-_____ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

# Week 72
# (Post 18th cycle of treatment)

**M9**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 72]**
**Post 18th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 72

**Instructions:** The post 18th cycle of treatment [72 weeks] imaging and reports are reviewed and the form is completed by the study Radiologist. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as MM/DD/YYYY. All responses are required unless otherwise noted.

## General Imaging Information

**1. Was MRI imaging performed at this visit?** [1]
- O No (*complete Q1a and Q15, then stop and sign form*)
- O Yes

**1a.** Reason imaging not performed: *(check only one)* [2]
- O Scheduling Problem
- O Equipment failure
- O Patient refusal
- O Medical contraindication
- O Injection site complications
- O Claustrophobia
- O Other, Specify _____ [3]

**1b.** Reader ID |_|_|_|_|_|_|_| [4]

**1c.** Is the image quality sufficient for analysis? [5]
- O No
- O Yes

**1d.** Was the scanner used for this exam the same as at baseline? [6]
- O No
- O Yes

**2. Date of MRI:** ____-____-____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]
- O No
- O Yes

**2b.** Was T1 weighted post-contrast imaging performed? [9]
- O No
- O Yes

**2c.** Was T2 weighted imaging performed? [10]
- O No
- O Yes

**2d.** Was FLAIR imaging performed? [11]
- O No
- O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]
- O No
- O Yes

**3. Patient weight** |_|_|_|.|_|_| **kg** (measured on day of scan) [16]

**4. Time of injection (military time)** |_|_|:|_|_| [17]

**5. Contrast administration dose** |_|_|.|_|_| **mmol/kg** [18]

**6. Volume of contrast injection** |_|_|.|_|_| **cc** [20]

**7. Brand of contrast agent injected** *(check only one)* [28]
- O Magnevist
- O Omniscan
- O ProHance
- O OptiMark
- O Other, specify _____ [29]

**8. Scan start time (military time)** |_|_|:|_|_| [30]

**9. Scan stop time (military time)** |_|_|:|_|_| [31]

**M9**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 72]**
**Post 18th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# WEEK 72

## MRI Assessment [72 Weeks] Post 18th Cycle of Treatment

**10a.** Are lesions present? [32]

O No (Complete only Q10g and Q15, then sign and date form)
O Yes

**10b.** Series number and slice number used for measurement

**Series Number** ____ [33]

**Slice Number** ____ [34]

**10c.** Largest Cross-sectional Diameter

____.____ mm [35]

**10d.** Largest Perpendicular Diameter

____.____ mm [36]

**10e.** Location Of Primary
*(mark all that apply with a check; ☐ = 1 not marked; ☑ = 2 marked)*

☐ Frontal lobe [37]
☐ Temporal lobe [38]
☐ Parietal lobe [39]
☐ Occipital lobe [40]
☐ Deep (Basal Ganglia/Thalamus) [41]
☐ Cerebellum [42]
☐ Brainstem [43]
☐ Corpus Callosum [44]
☐ Spinal Cord [45]
☐ Other, [46] Specify _____ [47]

**10f.** Lateralization of Tumor [48]

O Right
O Left
O Bilateral

**10g.** Scan Response [49]

O CR
O PR
O Stable
O Progression
O Not able to be assessed; specify reason

_____ [50]

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC and FA:**

**11. Series number and slice number used for measurement**

**Series Number** ____ [51] ☐ **N/A** [83]

**Slice Number** ____ [52] ☐ **N/A** [84]

**12. Center of enhancing mass (in enhancing area):**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [53] ☐ **N/A** [77]

**Mean FA** ____.____ [54] ☐ **N/A** [78]

**13. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [59] ☐ **N/A** [79]

**Mean FA** ____.____ [60] ☐ **N/A** [80]

**14. In normal appearing tissue**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [65] ☐ **N/A** [81]

**Mean FA** ____.____ [66] ☐ **N/A** [82]

## Interval Scans

**15. Were any MRI scans performed since last visit excluding today's scan?** [71]

O No
O Yes (Report interval scan results on form B1)

**15a.** Number of interval scans performed ____ [72]

**Note: Submit a separate form B1 for each interval scan performed.**

**M9**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 72]**
**Post 18th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 72

**COMMENTS:** _____

_____

_____

_____ [73]

_____ [74]
Radiologist responsible for data

_____-_____-_____ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

**V9**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Week 72**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 72

**Instructions:** The advanced MRI imaging and reports are reviewed and the form is completed by the study Radiologist. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as mm/dd/yyyy. All responses are required unless otherwise noted.

## General Imaging Information

**1. Was Advanced MRI imaging performed at this visit?** [1]
- O No (*complete Q1a then skip to Q18*)
- O Yes

**1a.** Reason imaging not performed: *(check only one)* [2]
- O Scheduling Problem
- O Equipment failure
- O Patient refusal
- O Medical contraindication
- O Injection site complications
- O Claustrophobia
- O Other, Specify _____ [3]

**1b.** Reader ID |_|_|_|_|_|_|_|_| [4]

**1c.** Is the image quality sufficient for analysis? [5]
- O No
- O Yes

**1d.** Was the scanner used for this exam the same as at baseline? [6]
- O No
- O Yes

**2. Date of advanced MRI:** _____-_____-_____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]
- O No
- O Yes

**2b.** Was T-1 weighted post-contrast imaging performed? [9]
- O No
- O Yes

**2c.** Was T2 weighted imaging performed? [10]
- O No
- O Yes

**2d.** Was FLAIR imaging performed? [11]
- O No
- O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]
- O No
- O Yes

**2f.** Was DCE imaging performed? [13]
- O No
- O Yes

**2g.** Was DSC imaging performed? [14]
- O No
- O Yes

**2h.** Was MRS/MRSI imaging performed? [15]
- O No
- O Yes

**3. Patient weight** (measured on day of scan) [16]
|_|_|_|.|_| **kg**

**4. Time of injection** (military time) |_|_|:|_|_| [17]

**5. Contrast administration dose** |_|_|.|_|_| **mmol/kg** [18]

**6. Rate of injection** |_|_|.|_|_| **cc/sec** [19]

**7. Volume of contrast injection** |_|_|.|_|_| **cc** [20]

**8. Volume of saline injection** |_|_|.|_|_| **cc** [21]

**9. Was second injection performed?** [22]
- O No (skip to Q10)
- O Yes

**9a. Time of second injection** [23]
(military time) |_|_|:|_|_|

# WEEK 72

**9b.** Contrast administration dose of second injection *(skip if second injection not performed)*
___.___ mmol/kg [24]

**9c.** Rate of second injection ___.___ cc/sec
*(skip if second injection not performed)* [25]

**9d.** Volume of second contrast injection ___.___ cc
*(skip if second injection not performed)* [26]

**9e.** Volume of second saline injection ___.___ cc
*(skip if second injection not performed)* [27]

**10. Brand of contrast agent injected** *(check only one)* [28]

O Magnevist
O Omniscan
O ProHance
O OptiMark
O Other, specify _____ [29]

**11. Scan start time (military time)** ___:___ [30]

**12. Scan stop time (military time)** ___:___ [31]

## Week 72 Advanced Imaging Scans

**13a.** Are lesions present? [32]

O No *(complete Q13g then skip to Q18)*
O Yes

**13b.** Series number and slice number used for measurement

**Series Number** _____ [33]

**Slice Number** _____ [34]

**13c.** Largest Cross-sectional Diameter

___.___ mm [35]

**13d.** Largest Perpendicular Diameter

___.___ mm [36]

**13e.** Location Of Primary (check all that apply)

☐ Frontal lobe [37]
☐ Temporal lobe [38]
☐ Parietal lobe [39]
☐ Occipital lobe [40]
☐ Deep (Basal Ganglia/Thalamus) [41]
☐ Cerebellum [42]
☐ Brainstem [43]
☐ Corpus Callosum [44]
☐ Spinal Cord [45]
☐ Other, [46] Specify _____ [47]

**13f.** Lateralization of Tumor [48]

O Right
O Left
O Bilateral

**13g.** Scan Response [49]

O CR
O PR
O Stable
O Progression
O Not able to be assessed; specify reason

_____ [50]

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC, FA, CBV, Ktrans, Other local permeability, and Choline/NAA ratio:**

**14. Series number and slice number used for measurement**

**Series Number** _____ [51] ☐ **N/A** [95]

**Slice Number** _____ [52] ☐ **N/A** [96]

**V9**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Week 72**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 72

**15. Center of enhancing mass (in enhancing area):**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ___.___ [53] ☐ **N/A** [77]

**Mean FA** ___.___ [54] ☐ **N/A** [78]

**Mean CBV** ___.___ [55] ☐ **N/A** [79]

**Mean Ktrans** ___.___ [56] ☐ **N/A** [80]

**Mean Other local permeability**

___.___ [57] ☐ **N/A** [81]

**Mean Choline/NAA ratio**

___.___ [58] ☐ **N/A** [82]

**16. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ___.___ [59] ☐ **N/A** [83]

**Mean FA** ___.___ [60] ☐ **N/A** [84]

**Mean CBV** ___.___ [61] ☐ **N/A** [85]

**Mean Ktrans** ___.___ [62] ☐ **N/A** [86]

**Mean Other local permeability**

___.___ [63] ☐ **N/A** [87]

**Mean Choline/NAA ratio**

___.___ [64] ☐ **N/A** [88]

**17. In normal-appearing tissue**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ___.___ [65] ☐ **N/A** [89]

**Mean FA** ___.___ [66] ☐ **N/A** [90]

**Mean CBV** ___.___ [67] ☐ **N/A** [91]

**Mean Ktrans** ___.___ [68] ☐ **N/A** [92]

**Mean Other local permeability**

___.___ [69] ☐ **N/A** [93]

**Mean Choline/NAA ratio:**

___.___ [70] ☐ **N/A** [94]

## Interval Scans

**18. Were any MRI scans performed since last visit excluding today's scan?** [71]

- O No
- O Yes *(report interval scan results on form G1)*

18a. Number of interval scans performed ___ [72]

**Note: Submit a separate form G1 for each interval scan performed.**

**Comments:** _____

_____ [73]

_____ [74]
Radiologist responsible for data

__-__-__ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

# Week 80
# (Post 20th cycle of treatment)

**MA**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 80]**
**Post 20th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# WEEK 80

**Instructions:** The post 20th cycle of treatment [80 weeks] imaging and reports are reviewed and the form is completed by the study Radiologist. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as MM/DD/YYYY. All responses are required unless otherwise noted.

## General Imaging Information

**1. Was MRI imaging performed at this visit?** [1]
- O No (*complete Q1a and Q15, then stop and sign form*)
- O Yes

**1a.** Reason imaging not performed: *(check only one)* [2]
- O Scheduling Problem
- O Equipment failure
- O Patient refusal
- O Medical contraindication
- O Injection site complications
- O Claustrophobia
- O Other, Specify _____ [3]

**1b.** Reader ID |_|_|_|_|_|_|_| [4]

**1c.** Is the image quality sufficient for analysis? [5]
- O No
- O Yes

**1d.** Was the scanner used for this exam the same as at baseline? [6]
- O No
- O Yes

**2. Date of MRI:** ____-____-____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]
- O No
- O Yes

**2b.** Was T1 weighted post-contrast imaging performed? [9]
- O No
- O Yes

**2c.** Was T2 weighted imaging performed? [10]
- O No
- O Yes

**2d.** Was FLAIR imaging performed? [11]
- O No
- O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]
- O No
- O Yes

**3. Patient weight** |_|_|_|.|_|_| **kg** (measured on day of scan) [16]

**4. Time of injection (military time)** |_|_|:|_|_| [17]

**5. Contrast administration dose** |_|_|.|_|_| **mmol/kg** [18]

**6. Volume of contrast injection** |_|_|.|_|_| **cc** [20]

**7. Brand of contrast agent injected** *(check only one)* [28]
- O Magnevist
- O Omniscan
- O ProHance
- O OptiMark
- O Other, specify _____ [29]

**8. Scan start time (military time)** |_|_|:|_|_| [30]

**9. Scan stop time (military time)** |_|_|:|_|_| [31]

**MA**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 80]**
**Post 20th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# WEEK 80

## MRI Assessment [80 Weeks] Post 20th Cycle of Treatment

**10a.** Are lesions present? [32]
- O No (Complete only Q10g and Q15, then sign and date form)
- O Yes

**10b.** Series number and slice number used for measurement

**Series Number** ☐☐☐☐☐ [33]

**Slice Number** ☐☐☐☐☐ [34]

**10c.** Largest Cross-sectional Diameter

☐☐☐.☐ mm [35]

**10d.** Largest Perpendicular Diameter

☐☐☐.☐ mm [36]

**10e.** Location Of Primary
*(mark all that apply with a check; ☐ = 1 not marked; ☑ = 2 marked)*

- ☐ Frontal lobe [37]
- ☐ Temporal lobe [38]
- ☐ Parietal lobe [39]
- ☐ Occipital lobe [40]
- ☐ Deep (Basal Ganglia/Thalamus) [41]
- ☐ Cerebellum [42]
- ☐ Brainstem [43]
- ☐ Corpus Callosum [44]
- ☐ Spinal Cord [45]
- ☐ Other, [46] Specify _____ [47]

**10f.** Lateralization of Tumor [48]
- O Right
- O Left
- O Bilateral

**10g.** Scan Response [49]
- O CR
- O PR
- O Stable
- O Progression
- O Not able to be assessed; specify reason

_____ [50]

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC and FA:**

**11. Series number and slice number used for measurement**

**Series Number** ☐☐☐☐☐ [51] ☐ **N/A** [83]

**Slice Number** ☐☐☐☐☐ [52] ☐ **N/A** [84]

**12. Center of enhancing mass (in enhancing area):**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ☐☐☐☐☐.☐☐☐☐ [53] ☐ **N/A** [77]

**Mean FA** ☐☐☐☐☐.☐☐☐☐ [54] ☐ **N/A** [78]

**13. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ☐☐☐☐☐.☐☐☐☐ [59] ☐ **N/A** [79]

**Mean FA** ☐☐☐☐☐.☐☐☐☐ [60] ☐ **N/A** [80]

**14. In normal appearing tissue**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ☐☐☐☐☐.☐☐☐☐ [65] ☐ **N/A** [81]

**Mean FA** ☐☐☐☐☐.☐☐☐☐ [66] ☐ **N/A** [82]

## Interval Scans

**15. Were any MRI scans performed since last visit excluding today's scan?** [71]
- O No
- O Yes (Report interval scan results on form B1)

**15a.** Number of interval scans performed ☐☐ [72]

**Note: Submit a separate form B1 for each interval scan performed.**

**MA**

## ACRIN 6677 / RTOG 0625

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 80]**
**Post 20th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# WEEK 80

**COMMENTS:** _____

_____

_____

_____ [73]

_____ [74]
Radiologist responsible for data

_____-_____-_____ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

**VA**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Week 80**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# WEEK 80

**Instructions:** The advanced MRI imaging and reports are reviewed and the form is completed by the study Radiologist. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as mm/dd/yyyy. All responses are required unless otherwise noted.

## General Imaging Information

**1. Was Advanced MRI imaging performed at this visit?** [1]
- O No (*complete Q1a then skip to Q18*)
- O Yes

**1a.** Reason imaging not performed: *(check only one)* [2]
- O Scheduling Problem
- O Equipment failure
- O Patient refusal
- O Medical contraindication
- O Injection site complications
- O Claustrophobia
- O Other, Specify _____ [3]

**1b.** Reader ID ☐☐☐☐☐☐☐ [4]

**1c.** Is the image quality sufficient for analysis? [5]
- O No
- O Yes

**1d.** Was the scanner used for this exam the same as at baseline? [6]
- O No
- O Yes

**2. Date of advanced MRI:** _____-_____-_____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]
- O No
- O Yes

**2b.** Was T-1 weighted post-contrast imaging performed? [9]
- O No
- O Yes

**2c.** Was T2 weighted imaging performed? [10]
- O No
- O Yes

**2d.** Was FLAIR imaging performed? [11]
- O No
- O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]
- O No
- O Yes

**2f.** Was DCE imaging performed? [13]
- O No
- O Yes

**2g.** Was DSC imaging performed? [14]
- O No
- O Yes

**2h.** Was MRS/MRSI imaging performed? [15]
- O No
- O Yes

**3. Patient weight** (measured on day of scan) [16]
☐☐☐.☐ **kg**

**4. Time of injection** (military time) ☐☐:☐☐ [17]

**5. Contrast administration dose** ☐☐.☐☐ **mmol/kg** [18]

**6. Rate of injection** ☐☐.☐☐ **cc/sec** [19]

**7. Volume of contrast injection** ☐☐.☐☐ **cc** [20]

**8. Volume of saline injection** ☐☐.☐☐ **cc** [21]

**9. Was second injection performed?** [22]
- O No (skip to Q10)
- O Yes

**9a. Time of second injection** [23]
(military time) ☐☐:☐☐

# WEEK 80

**9b.** Contrast administration dose of second injection *(skip if second injection not performed)*
___.___ mmol/kg [24]

**9c.** Rate of second injection ___.___ cc/sec
*(skip if second injection not performed)* [25]

**9d.** Volume of second contrast injection ___.___ cc
*(skip if second injection not performed)* [26]

**9e.** Volume of second saline injection ___.___ cc
*(skip if second injection not performed)* [27]

**10. Brand of contrast agent injected** *(check only one)* [28]

- O Magnevist
- O Omniscan
- O ProHance
- O OptiMark
- O Other, specify _____ [29]

**11. Scan start time (military time)** ___:___ [30]

**12. Scan stop time (military time)** ___:___ [31]

## Week 80 Advanced Imaging Scans

**13a.** Are lesions present? [32]

- O No *(complete Q13g then skip to Q18)*
- O Yes

**13b.** Series number and slice number used for measurement

**Series Number** _____ [33]

**Slice Number** _____ [34]

**13c.** Largest Cross-sectional Diameter

___.___ mm [35]

**13d.** Largest Perpendicular Diameter

___.___ mm [36]

**13e.** Location Of Primary (check all that apply)

- ☐ Frontal lobe [37]
- ☐ Temporal lobe [38]
- ☐ Parietal lobe [39]
- ☐ Occipital lobe [40]
- ☐ Deep (Basal Ganglia/Thalamus) [41]
- ☐ Cerebellum [42]
- ☐ Brainstem [43]
- ☐ Corpus Callosum [44]
- ☐ Spinal Cord [45]
- ☐ Other, [46] Specify _____ [47]

**13f.** Lateralization of Tumor [48]

- O Right
- O Left
- O Bilateral

**13g.** Scan Response [49]

- O CR
- O PR
- O Stable
- O Progression
- O Not able to be assessed; specify reason

_____ [50]

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC, FA, CBV, Ktrans, Other local permeability, and Choline/NAA ratio:**

**14. Series number and slice number used for measurement**

**Series Number** _____ [51] ☐ **N/A** [95]

**Slice Number** _____ [52] ☐ **N/A** [96]

**VA**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Week 80**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 80

**15. Center of enhancing mass (in enhancing area):**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ___.___ [53] ☐ **N/A** [77]

**Mean FA** ___.___ [54] ☐ **N/A** [78]

**Mean CBV** ___.___ [55] ☐ **N/A** [79]

**Mean Ktrans** ___.___ [56] ☐ **N/A** [80]

**Mean Other local permeability**

___.___ [57] ☐ **N/A** [81]

**Mean Choline/NAA ratio**

___.___ [58] ☐ **N/A** [82]

**16. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ___.___ [59] ☐ **N/A** [83]

**Mean FA** ___.___ [60] ☐ **N/A** [84]

**Mean CBV** ___.___ [61] ☐ **N/A** [85]

**Mean Ktrans** ___.___ [62] ☐ **N/A** [86]

**Mean Other local permeability**

___.___ [63] ☐ **N/A** [87]

**Mean Choline/NAA ratio**

___.___ [64] ☐ **N/A** [88]

**17. In normal-appearing tissue**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ___.___ [65] ☐ **N/A** [89]

**Mean FA** ___.___ [66] ☐ **N/A** [90]

**Mean CBV** ___.___ [67] ☐ **N/A** [91]

**Mean Ktrans** ___.___ [68] ☐ **N/A** [92]

**Mean Other local permeability**

___.___ [69] ☐ **N/A** [93]

**Mean Choline/NAA ratio:**

___.___ [70] ☐ **N/A** [94]

## Interval Scans

**18. Were any MRI scans performed since last visit excluding today's scan?** [71]

O No
O Yes *(report interval scan results on form G1)*

18a. Number of interval scans performed ___ [72]

**Note: Submit a separate form G1 for each interval scan performed.**

**Comments:** _____

_____ [73]

_____ [74]
Radiologist responsible for data

__-__-____ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

# Week 88
# (Post 22nd cycle of treatment)

**MB**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 88]**
**Post 22nd Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# WEEK 88

**Instructions:** The post 22nd cycle of treatment [88 weeks] imaging and reports are reviewed and the form is completed by the study Radiologist. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as MM/DD/YYYY. All responses are required unless otherwise noted.

## General Imaging Information

**1. Was MRI imaging performed at this visit?** [1]

O No (*complete Q1a and Q15, then stop and sign form*)
O Yes

**1a.** Reason imaging not performed: *(check only one)* [2]

O Scheduling Problem
O Equipment failure
O Patient refusal
O Medical contraindication
O Injection site complications
O Claustrophobia
O Other, Specify _____ [3]

**1b.** Reader ID |_|_|_|_|_|_|_| [4]

**1c.** Is the image quality sufficient for analysis? [5]

O No
O Yes

**1d.** Was the scanner used for this exam the same as at baseline? [6]

O No
O Yes

**2. Date of MRI:** ____-____-____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]

O No
O Yes

**2b.** Was T1 weighted post-contrast imaging performed? [9]

O No
O Yes

**2c.** Was T2 weighted imaging performed? [10]

O No
O Yes

**2d.** Was FLAIR imaging performed? [11]

O No
O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]

O No
O Yes

**3. Patient weight** |_|_|_|.|_| **kg** (measured on day of scan) [16]

**4. Time of injection (military time)** |_|_|:|_|_| [17]

**5. Contrast administration dose** |_|_|.|_|_| **mmol/kg** [18]

**6. Volume of contrast injection** |_|_|.|_|_| **cc** [20]

**7. Brand of contrast agent injected** *(check only one)* [28]

O Magnevist
O Omniscan
O ProHance
O OptiMark
O Other, specify _____ [29]

**8. Scan start time (military time)** |_|_|:|_|_| [30]

**9. Scan stop time (military time)** |_|_|:|_|_| [31]

**MB**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 88]**
**Post 22nd Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# WEEK 88

## MRI Assessment [88 Weeks] Post 22nd Cycle of Treatment

**10a.** Are lesions present? [32]

O No (Complete only Q10g and Q15, then sign and date form)
O Yes

**10b.** Series number and slice number used for measurement

**Series Number** ____ [33]

**Slice Number** ____ [34]

**10c.** Largest Cross-sectional Diameter

____.____ mm [35]

**10d.** Largest Perpendicular Diameter

____.____ mm [36]

**10e.** Location Of Primary
*(mark all that apply with a check; ☐ = 1 not marked; ☑ = 2 marked)*

☐ Frontal lobe [37]
☐ Temporal lobe [38]
☐ Parietal lobe [39]
☐ Occipital lobe [40]
☐ Deep (Basal Ganglia/Thalamus) [41]
☐ Cerebellum [42]
☐ Brainstem [43]
☐ Corpus Callosum [44]
☐ Spinal Cord [45]
☐ Other, [46] Specify _____ [47]

**10f.** Lateralization of Tumor [48]

O Right
O Left
O Bilateral

**10g.** Scan Response [49]

O CR
O PR
O Stable
O Progression
O Not able to be assessed; specify reason

_____ [50]

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC and FA:**

**11. Series number and slice number used for measurement**

**Series Number** ____ [51] ☐ **N/A** [83]

**Slice Number** ____ [52] ☐ **N/A** [84]

**12. Center of enhancing mass (in enhancing area):**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [53] ☐ **N/A** [77]

**Mean FA** ____.____ [54] ☐ **N/A** [78]

**13. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [59] ☐ **N/A** [79]

**Mean FA** ____.____ [60] ☐ **N/A** [80]

**14. In normal appearing tissue**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [65] ☐ **N/A** [81]

**Mean FA** ____.____ [66] ☐ **N/A** [82]

## Interval Scans

**15. Were any MRI scans performed since last visit excluding today's scan?** [71]

O No
O Yes (Report interval scan results on form B1)

**15a.** Number of interval scans performed ____ [72]

**Note: Submit a separate form B1 for each interval scan performed.**

**MB**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 88]**
**Post 22nd Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# WEEK 88

**COMMENTS:** _____

_____

_____

_____ [73]

_____ [74]
Radiologist responsible for data

_____-_____-_____ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

**VB**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Week 88**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# WEEK 88

**Instructions:** The advanced MRI imaging and reports are reviewed and the form is completed by the study Radiologist. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as mm/dd/yyyy. All responses are required unless otherwise noted.

## General Imaging Information

**1. Was Advanced MRI imaging performed at this visit?** [1]
- O No (*complete Q1a then skip to Q18*)
- O Yes

**1a.** Reason imaging not performed: *(check only one)* [2]
- O Scheduling Problem
- O Equipment failure
- O Patient refusal
- O Medical contraindication
- O Injection site complications
- O Claustrophobia
- O Other, Specify _____ [3]

**1b.** Reader ID |_|_|_|_|_|_|_|_| [4]

**1c.** Is the image quality sufficient for analysis? [5]
- O No
- O Yes

**1d.** Was the scanner used for this exam the same as at baseline? [6]
- O No
- O Yes

**2. Date of advanced MRI:** _____-_____-_____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]
- O No
- O Yes

**2b.** Was T-1 weighted post-contrast imaging performed? [9]
- O No
- O Yes

**2c.** Was T2 weighted imaging performed? [10]
- O No
- O Yes

**2d.** Was FLAIR imaging performed? [11]
- O No
- O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]
- O No
- O Yes

**2f.** Was DCE imaging performed? [13]
- O No
- O Yes

**2g.** Was DSC imaging performed? [14]
- O No
- O Yes

**2h.** Was MRS/MRSI imaging performed? [15]
- O No
- O Yes

**3. Patient weight** (measured on day of scan) [16]
|_|_|_|.|_| **kg**

**4. Time of injection** (military time) |_|_|:|_|_| [17]

**5. Contrast administration dose** |_|_|.|_|_| **mmol/kg** [18]

**6. Rate of injection** |_|_|.|_|_| **cc/sec** [19]

**7. Volume of contrast injection** |_|_|.|_|_| **cc** [20]

**8. Volume of saline injection** |_|_|.|_|_| **cc** [21]

**9. Was second injection performed?** [22]
- O No (skip to Q10)
- O Yes

**9a. Time of second injection** [23]
(military time) |_|_|:|_|_|

# WEEK 88

**9b.** Contrast administration dose of second injection *(skip if second injection not performed)*
___.___ mmol/kg [24]

**9c.** Rate of second injection ___.___ cc/sec *(skip if second injection not performed)* [25]

**9d.** Volume of second contrast injection ___.___ cc *(skip if second injection not performed)* [26]

**9e.** Volume of second saline injection ___.___ cc *(skip if second injection not performed)* [27]

**10. Brand of contrast agent injected** *(check only one)* [28]

- O Magnevist
- O Omniscan
- O ProHance
- O OptiMark
- O Other, specify _____ [29]

**11. Scan start time (military time)** ___:___ [30]

**12. Scan stop time (military time)** ___:___ [31]

## Week 88 Advanced Imaging Scans

**13a.** Are lesions present? [32]

- O No *(complete Q13g then skip to Q18)*
- O Yes

**13b.** Series number and slice number used for measurement

**Series Number** _____ [33]

**Slice Number** _____ [34]

**13c.** Largest Cross-sectional Diameter

___.___ mm [35]

**13d.** Largest Perpendicular Diameter

___.___ mm [36]

**13e.** Location Of Primary (check all that apply)

- ☐ Frontal lobe [37]
- ☐ Temporal lobe [38]
- ☐ Parietal lobe [39]
- ☐ Occipital lobe [40]
- ☐ Deep (Basal Ganglia/Thalamus) [41]
- ☐ Cerebellum [42]
- ☐ Brainstem [43]
- ☐ Corpus Callosum [44]
- ☐ Spinal Cord [45]
- ☐ Other, [46] Specify _____ [47]

**13f.** Lateralization of Tumor [48]

- O Right
- O Left
- O Bilateral

**13g.** Scan Response [49]

- O CR
- O PR
- O Stable
- O Progression
- O Not able to be assessed; specify reason

_____ [50]

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC, FA, CBV, Ktrans, Other local permeability, and Choline/NAA ratio:**

**14. Series number and slice number used for measurement**

**Series Number** _____ [51] ☐ **N/A** [95]

**Slice Number** _____ [52] ☐ **N/A** [96]

**VB**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Week 88**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# WEEK 88

**15. Center of enhancing mass (in enhancing area):**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ___.___ [53] ☐ **N/A** [77]

**Mean FA** ___.___ [54] ☐ **N/A** [78]

**Mean CBV** ___.___ [55] ☐ **N/A** [79]

**Mean Ktrans** ___.___ [56] ☐ **N/A** [80]

**Mean Other local permeability**

___.___ [57] ☐ **N/A** [81]

**Mean Choline/NAA ratio**

___.___ [58] ☐ **N/A** [82]

**16. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ___.___ [59] ☐ **N/A** [83]

**Mean FA** ___.___ [60] ☐ **N/A** [84]

**Mean CBV** ___.___ [61] ☐ **N/A** [85]

**Mean Ktrans** ___.___ [62] ☐ **N/A** [86]

**Mean Other local permeability**

___.___ [63] ☐ **N/A** [87]

**Mean Choline/NAA ratio**

___.___ [64] ☐ **N/A** [88]

**17. In normal-appearing tissue**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ___.___ [65] ☐ **N/A** [89]

**Mean FA** ___.___ [66] ☐ **N/A** [90]

**Mean CBV** ___.___ [67] ☐ **N/A** [91]

**Mean Ktrans** ___.___ [68] ☐ **N/A** [92]

**Mean Other local permeability**

___.___ [69] ☐ **N/A** [93]

**Mean Choline/NAA ratio:**

___.___ [70] ☐ **N/A** [94]

## Interval Scans

**18. Were any MRI scans performed since last visit excluding today's scan?** [71]

- O No
- O Yes *(report interval scan results on form G1)*

18a. Number of interval scans performed ___ [72]

**Note: Submit a separate form G1 for each interval scan performed.**

**Comments:** _____

_____ [73]

_____ [74]
Radiologist responsible for data

___-___-___ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

# Week 96
# (Post 24th cycle of treatment)

**MC**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 96]**
**Post 24th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# WEEK 96

**Instructions:** The post 24th cycle of treatment [96 weeks] imaging and reports are reviewed and the form is completed by the study Radiologist. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as MM/DD/YYYY. All responses are required unless otherwise noted.

## General Imaging Information

**1. Was MRI imaging performed at this visit?** [1]

O No (*complete Q1a and Q15, then stop and sign form*)
O Yes

**1a.** Reason imaging not performed: *(check only one)* [2]

O Scheduling Problem
O Equipment failure
O Patient refusal
O Medical contraindication
O Injection site complications
O Claustrophobia
O Other, Specify _____ [3]

**1b.** Reader ID |_|_|_|_|_|_|_| [4]

**1c.** Is the image quality sufficient for analysis? [5]

O No
O Yes

**1d.** Was the scanner used for this exam the same as at baseline? [6]

O No
O Yes

**2. Date of MRI:** ____-____-____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]

O No
O Yes

**2b.** Was T1 weighted post-contrast imaging performed? [9]

O No
O Yes

**2c.** Was T2 weighted imaging performed? [10]

O No
O Yes

**2d.** Was FLAIR imaging performed? [11]

O No
O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]

O No
O Yes

**3. Patient weight** |_|_|_|.|_| **kg** (measured on day of scan) [16]

**4. Time of injection (military time)** |_|_|:|_|_| [17]

**5. Contrast administration dose** |_|_|.|_|_| **mmol/kg** [18]

**6. Volume of contrast injection** |_|_|.|_|_| **cc** [20]

**7. Brand of contrast agent injected** *(check only one)* [28]

O Magnevist
O Omniscan
O ProHance
O OptiMark
O Other, specify _____ [29]

**8. Scan start time (military time)** |_|_|:|_|_| [30]

**9. Scan stop time (military time)** |_|_|:|_|_| [31]

**MC**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 96]**
**Post 24th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# WEEK 96

## MRI Assessment [96 Weeks] Post 24th Cycle of Treatment

**10a.** Are lesions present? [32]

O No (Complete only Q10g and Q15, then sign and date form)
O Yes

**10b.** Series number and slice number used for measurement

**Series Number** ____ [33]

**Slice Number** ____ [34]

**10c.** Largest Cross-sectional Diameter

____.____ mm [35]

**10d.** Largest Perpendicular Diameter

____.____ mm [36]

**10e.** Location Of Primary
*(mark all that apply with a check; ☐ = 1 not marked; ☑ = 2 marked)*

☐ Frontal lobe [37]
☐ Temporal lobe [38]
☐ Parietal lobe [39]
☐ Occipital lobe [40]
☐ Deep (Basal Ganglia/Thalamus) [41]
☐ Cerebellum [42]
☐ Brainstem [43]
☐ Corpus Callosum [44]
☐ Spinal Cord [45]
☐ Other, [46] Specify _____ [47]

**10f.** Lateralization of Tumor [48]

O Right
O Left
O Bilateral

**10g.** Scan Response [49]

O CR
O PR
O Stable
O Progression
O Not able to be assessed; specify reason

_____ [50]

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC and FA:**

**11. Series number and slice number used for measurement**

**Series Number** ____ [51] ☐ **N/A** [83]

**Slice Number** ____ [52] ☐ **N/A** [84]

**12. Center of enhancing mass (in enhancing area):**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [53] ☐ **N/A** [77]

**Mean FA** ____.____ [54] ☐ **N/A** [78]

**13. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [59] ☐ **N/A** [79]

**Mean FA** ____.____ [60] ☐ **N/A** [80]

**14. In normal appearing tissue**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [65] ☐ **N/A** [81]

**Mean FA** ____.____ [66] ☐ **N/A** [82]

## Interval Scans

**15. Were any MRI scans performed since last visit excluding today's scan?** [71]

O No
O Yes (Report interval scan results on form B1)

**15a.** Number of interval scans performed ____ [72]

**Note: Submit a separate form B1 for each interval scan performed.**

MC

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [week 96]**
**Post 24th Cycle of Treatment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 96

**COMMENTS:** _____

_____

_____

_____ [73]

_____ [74]
Radiologist responsible for data

_____-_____-_____ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

**VC**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Week 96**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 96

**Instructions:** The advanced MRI imaging and reports are reviewed and the form is completed by the study Radiologist. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as mm/dd/yyyy. All responses are required unless otherwise noted.

## General Imaging Information

**1. Was Advanced MRI imaging performed at this visit?** [1]
- O No (*complete Q1a then skip to Q18*)
- O Yes

**1a.** Reason imaging not performed: *(check only one)* [2]
- O Scheduling Problem
- O Equipment failure
- O Patient refusal
- O Medical contraindication
- O Injection site complications
- O Claustrophobia
- O Other, Specify _____ [3]

**1b.** Reader ID |_|_|_|_|_|_|_|_| [4]

**1c.** Is the image quality sufficient for analysis? [5]
- O No
- O Yes

**1d.** Was the scanner used for this exam the same as at baseline? [6]
- O No
- O Yes

**2. Date of advanced MRI:** _____-_____-_____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]
- O No
- O Yes

**2b.** Was T-1 weighted post-contrast imaging performed? [9]
- O No
- O Yes

**2c.** Was T2 weighted imaging performed? [10]
- O No
- O Yes

**2d.** Was FLAIR imaging performed? [11]
- O No
- O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]
- O No
- O Yes

**2f.** Was DCE imaging performed? [13]
- O No
- O Yes

**2g.** Was DSC imaging performed? [14]
- O No
- O Yes

**2h.** Was MRS/MRSI imaging performed? [15]
- O No
- O Yes

**3. Patient weight** (measured on day of scan) [16]
|_|_|_|.|_| **kg**

**4. Time of injection** (military time) |_|_|:|_|_| [17]

**5. Contrast administration dose** |_|_|.|_|_| **mmol/kg** [18]

**6. Rate of injection** |_|_|.|_|_| **cc/sec** [19]

**7. Volume of contrast injection** |_|_|.|_|_| **cc** [20]

**8. Volume of saline injection** |_|_|.|_|_| **cc** [21]

**9. Was second injection performed?** [22]
- O No (skip to Q10)
- O Yes

**9a. Time of second injection** [23]
(military time) |_|_|:|_|_|

# WEEK 96

**9b.** Contrast administration dose of second injection *(skip if second injection not performed)*
___.___ mmol/kg [24]

**9c.** Rate of second injection ___.___ cc/sec
*(skip if second injection not performed)* [25]

**9d.** Volume of second contrast injection ___.___ cc
*(skip if second injection not performed)* [26]

**9e.** Volume of second saline injection ___.___ cc
*(skip if second injection not performed)* [27]

**10. Brand of contrast agent injected** *(check only one)* [28]

- O Magnevist
- O Omniscan
- O ProHance
- O OptiMark
- O Other, specify _____ [29]

**11. Scan start time (military time)** ___:___ [30]

**12. Scan stop time (military time)** ___:___ [31]

## Week 96 Advanced Imaging Scans

**13a.** Are lesions present? [32]

- O No *(complete Q13g then skip to Q18)*
- O Yes

**13b.** Series number and slice number used for measurement

**Series Number** _____ [33]

**Slice Number** _____ [34]

**13c.** Largest Cross-sectional Diameter

___.___ mm [35]

**13d.** Largest Perpendicular Diameter

___.___ mm [36]

**13e.** Location Of Primary (check all that apply)

- ☐ Frontal lobe [37]
- ☐ Temporal lobe [38]
- ☐ Parietal lobe [39]
- ☐ Occipital lobe [40]
- ☐ Deep (Basal Ganglia/Thalamus) [41]
- ☐ Cerebellum [42]
- ☐ Brainstem [43]
- ☐ Corpus Callosum [44]
- ☐ Spinal Cord [45]
- ☐ Other, [46] Specify _____ [47]

**13f.** Lateralization of Tumor [48]

- O Right
- O Left
- O Bilateral

**13g.** Scan Response [49]

- O CR
- O PR
- O Stable
- O Progression
- O Not able to be assessed; specify reason

_____ [50]

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC, FA, CBV, Ktrans, Other local permeability, and Choline/NAA ratio:**

**14. Series number and slice number used for measurement**

**Series Number** _____ [51] ☐ **N/A** [95]

**Slice Number** _____ [52] ☐ **N/A** [96]

**VC**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Week 96**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## WEEK 96

**15. Center of enhancing mass (in enhancing area):**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [53] ☐ **N/A** [77]

**Mean FA** ____.____ [54] ☐ **N/A** [78]

**Mean CBV** ____.____ [55] ☐ **N/A** [79]

**Mean Ktrans** ____.____ [56] ☐ **N/A** [80]

**Mean Other local permeability**

____.____ [57] ☐ **N/A** [81]

**Mean Choline/NAA ratio**

____.____ [58] ☐ **N/A** [82]

**16. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [59] ☐ **N/A** [83]

**Mean FA** ____.____ [60] ☐ **N/A** [84]

**Mean CBV** ____.____ [61] ☐ **N/A** [85]

**Mean Ktrans** ____.____ [62] ☐ **N/A** [86]

**Mean Other local permeability**

____.____ [63] ☐ **N/A** [87]

**Mean Choline/NAA ratio**

____.____ [64] ☐ **N/A** [88]

**17. In normal-appearing tissue**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [65] ☐ **N/A** [89]

**Mean FA** ____.____ [66] ☐ **N/A** [90]

**Mean CBV** ____.____ [67] ☐ **N/A** [91]

**Mean Ktrans** ____.____ [68] ☐ **N/A** [92]

**Mean Other local permeability**

____.____ [69] ☐ **N/A** [93]

**Mean Choline/NAA ratio:**

____.____ [70] ☐ **N/A** [94]

## Interval Scans

**18. Were any MRI scans performed since last visit excluding today's scan?** [71]

- O No
- O Yes *(report interval scan results on form G1)*

18a. Number of interval scans performed ____ [72]

**Note: Submit a separate form G1 for each interval scan performed.**

**Comments:** _____

_____ [73]

_____ [74]
Radiologist responsible for data

____-____-____ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

# Final
# (Off-Study Assessment)

**MD**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [final]**
**Off-Study Assessment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

**FINAL**

**Instructions:** The off-study assessment [final] imaging and reports are reviewed and the form is completed by the study Radiologist. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as MM/DD/YYYY. All responses are required unless otherwise noted.

## General Imaging Information

**1. Was MRI imaging performed at this visit?** [1]
- O No (*complete Q1a and Q15, then stop and sign form*)
- O Yes

**1a.** Reason imaging not performed: *(check only one)* [2]
- O Scheduling Problem
- O Equipment failure
- O Patient refusal
- O Medical contraindication
- O Injection site complications
- O Claustrophobia
- O Other, Specify _____ [3]

**1b.** Reader ID |_|_|_|_|_|_|_| [4]

**1c.** Is the image quality sufficient for analysis? [5]
- O No
- O Yes

**1d.** Was the scanner used for this exam the same as at baseline? [6]
- O No
- O Yes

**2. Date of MRI:** ____-____-____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]
- O No
- O Yes

**2b.** Was T1 weighted post-contrast imaging performed? [9]
- O No
- O Yes

**2c.** Was T2 weighted imaging performed? [10]
- O No
- O Yes

**2d.** Was FLAIR imaging performed? [11]
- O No
- O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]
- O No
- O Yes

**3. Patient weight** |_|_|_|.|_| **kg** (measured on day of scan) [16]

**4. Time of injection (military time)** |_|_|:|_|_| [17]

**5. Contrast administration dose** |_|_|.|_|_| **mmol/kg** [18]

**6. Volume of contrast injection** |_|_|.|_|_| **cc** [20]

**7. Brand of contrast agent injected** *(check only one)* [28]
- O Magnevist
- O Omniscan
- O ProHance
- O OptiMark
- O Other, specify _____ [29]

**8. Scan start time (military time)** |_|_|:|_|_| [30]

**9. Scan stop time (military time)** |_|_|:|_|_| [31]

**MD**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [final]**
**Off-Study Assessment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

**FINAL**

## MRI Assessment [final]
## Off-Study Assessment

**10a.** Are lesions present? [32]

O No (Complete only Q10g and Q15, then sign and date form)
O Yes

**10b.** Series number and slice number used for measurement

**Series Number** ☐☐☐☐☐ [33]

**Slice Number** ☐☐☐☐☐ [34]

**10c.** Largest Cross-sectional Diameter

☐☐☐.☐ mm [35]

**10d.** Largest Perpendicular Diameter

☐☐☐.☐ mm [36]

**10e.** Location Of Primary
*(mark all that apply with a check; ☐ = 1 not marked; ☑ = 2 marked)*

☐ Frontal lobe [37]
☐ Temporal lobe [38]
☐ Parietal lobe [39]
☐ Occipital lobe [40]
☐ Deep (Basal Ganglia/Thalamus) [41]
☐ Cerebellum [42]
☐ Brainstem [43]
☐ Corpus Callosum [44]
☐ Spinal Cord [45]
☐ Other, [46] Specify _____ [47]

**10f.** Lateralization of Tumor [48]

O Right
O Left
O Bilateral

**10g.** Scan Response [49]

O CR
O PR
O Stable
O Progression
O Not able to be assessed; specify reason

_____ [50]

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC and FA:**

**11. Series number and slice number used for measurement**

**Series Number** ☐☐☐☐☐ [51] ☐ **N/A** [83]

**Slice Number** ☐☐☐☐☐ [52] ☐ **N/A** [84]

**12. Center of enhancing mass (in enhancing area):**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ☐☐☐☐☐.☐☐☐☐ [53] ☐ **N/A** [77]

**Mean FA** ☐☐☐☐☐.☐☐☐☐ [54] ☐ **N/A** [78]

**13. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ☐☐☐☐☐.☐☐☐☐ [59] ☐ **N/A** [79]

**Mean FA** ☐☐☐☐☐.☐☐☐☐ [60] ☐ **N/A** [80]

**14. In normal appearing tissue**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ☐☐☐☐☐.☐☐☐☐ [65] ☐ **N/A** [81]

**Mean FA** ☐☐☐☐☐.☐☐☐☐ [66] ☐ **N/A** [82]

## Interval Scans

**15. Were any MRI scans performed since last visit excluding today's scan?** [71]

O No
O Yes (Report interval scan results on form B1)

**15a.** Number of interval scans performed ☐☐ [72]

**Note: Submit a separate form B1 for each interval scan performed.**

**MD**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form [final]**
**Off-Study Assessment**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

**FINAL**

**COMMENTS:** _____

_____

_____

_____ [73]

_____ [74]
Radiologist responsible for data

_____-_____-_____ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

**VD**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Off-Study**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# OFF-STUDY

**Instructions:** The advanced MRI imaging and reports are reviewed and the form is completed by the study Radiologist. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as mm/dd/yyyy. All responses are required unless otherwise noted.

## General Imaging Information

**1. Was Advanced MRI imaging performed at this visit?** [1]
- O No (*complete Q1a then skip to Q18*)
- O Yes

**1a.** Reason imaging not performed: *(check only one)* [2]
- O Scheduling Problem
- O Equipment failure
- O Patient refusal
- O Medical contraindication
- O Injection site complications
- O Claustrophobia
- O Other, Specify _____ [3]

**1b.** Reader ID ☐☐☐☐☐☐☐☐ [4]

**1c.** Is the image quality sufficient for analysis? [5]
- O No
- O Yes

**1d.** Was the scanner used for this exam the same as at baseline? [6]
- O No
- O Yes

**2. Date of advanced MRI:** _____-_____-_____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]
- O No
- O Yes

**2b.** Was T-1 weighted post-contrast imaging performed? [9]
- O No
- O Yes

**2c.** Was T2 weighted imaging performed? [10]
- O No
- O Yes

**2d.** Was FLAIR imaging performed? [11]
- O No
- O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]
- O No
- O Yes

**2f.** Was DCE imaging performed? [13]
- O No
- O Yes

**2g.** Was DSC imaging performed? [14]
- O No
- O Yes

**2h.** Was MRS/MRSI imaging performed? [15]
- O No
- O Yes

**3. Patient weight** (measured on day of scan) [16]
☐☐☐.☐ **kg**

**4. Time of injection** (military time) ☐☐:☐☐ [17]

**5. Contrast administration dose** ☐☐.☐☐ **mmol/kg** [18]

**6. Rate of injection** ☐☐.☐☐ **cc/sec** [19]

**7. Volume of contrast injection** ☐☐.☐☐ **cc** [20]

**8. Volume of saline injection** ☐☐.☐☐ **cc** [21]

**9. Was second injection performed?** [22]
- O No (skip to Q10)
- O Yes

**9a. Time of second injection** [23]
(military time) ☐☐:☐☐

# OFF-STUDY

**9b.** Contrast administration dose of second injection *(skip if second injection not performed)*
___.___ mmol/kg [24]

**9c.** Rate of second injection ___.___ cc/sec
*(skip if second injection not performed)* [25]

**9d.** Volume of second contrast injection ___.___ cc
*(skip if second injection not performed)* [26]

**9e.** Volume of second saline injection ___.___ cc
*(skip if second injection not performed)* [27]

**10. Brand of contrast agent injected** *(check only one)* [28]

- O Magnevist
- O Omniscan
- O ProHance
- O OptiMark
- O Other, specify _____ [29]

**11. Scan start time (military time)** __:__ [30]

**12. Scan stop time (military time)** __:__ [31]

## Off-Study Advanced Imaging Scans

**13a.** Are lesions present? [32]

- O No *(complete Q13g then skip to Q18)*
- O Yes

**13b.** Series number and slice number used for measurement

**Series Number** _____ [33]

**Slice Number** _____ [34]

**13c.** Largest Cross-sectional Diameter

___.___ mm [35]

**13d.** Largest Perpendicular Diameter

___.___ mm [36]

**13e.** Location Of Primary (check all that apply)

- ☐ Frontal lobe [37]
- ☐ Temporal lobe [38]
- ☐ Parietal lobe [39]
- ☐ Occipital lobe [40]
- ☐ Deep (Basal Ganglia/Thalamus) [41]
- ☐ Cerebellum [42]
- ☐ Brainstem [43]
- ☐ Corpus Callosum [44]
- ☐ Spinal Cord [45]
- ☐ Other, [46] Specify _____ [47]

**13f.** Lateralization of Tumor [48]

- O Right
- O Left
- O Bilateral

**13g.** Scan Response [49]

- O CR
- O PR
- O Stable
- O Progression
- O Not able to be assessed; specify reason

_____ [50]

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC, FA, CBV, Ktrans, Other local permeability, and Choline/NAA ratio:**

**14. Series number and slice number used for measurement**

**Series Number** _____ [51] ☐ **N/A** [95]

**Slice Number** _____ [52] ☐ **N/A** [96]

**VD**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Off-Study**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# OFF-STUDY

**15. Center of enhancing mass (in enhancing area):**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ___.___ [53] ☐ **N/A** [77]

**Mean FA** ___.___ [54] ☐ **N/A** [78]

**Mean CBV** ___.___ [55] ☐ **N/A** [79]

**Mean Ktrans** ___.___ [56] ☐ **N/A** [80]

**Mean Other local permeability**

___.___ [57] ☐ **N/A** [81]

**Mean Choline/NAA ratio**

___.___ [58] ☐ **N/A** [82]

**16. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ___.___ [59] ☐ **N/A** [83]

**Mean FA** ___.___ [60] ☐ **N/A** [84]

**Mean CBV** ___.___ [61] ☐ **N/A** [85]

**Mean Ktrans** ___.___ [62] ☐ **N/A** [86]

**Mean Other local permeability**

___.___ [63] ☐ **N/A** [87]

**Mean Choline/NAA ratio**

___.___ [64] ☐ **N/A** [88]

**17. In normal-appearing tissue**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ___.___ [65] ☐ **N/A** [89]

**Mean FA** ___.___ [66] ☐ **N/A** [90]

**Mean CBV** ___.___ [67] ☐ **N/A** [91]

**Mean Ktrans** ___.___ [68] ☐ **N/A** [92]

**Mean Other local permeability**

___.___ [69] ☐ **N/A** [93]

**Mean Choline/NAA ratio:**

___.___ [70] ☐ **N/A** [94]

## Interval Scans

**18. Were any MRI scans performed since last visit excluding today's scan?** [71]

- O No
- O Yes *(report interval scan results on form G1)*

18a. Number of interval scans performed ___ [72]

**Note: Submit a separate form G1 for each interval scan performed.**

**Comments:** _____

_____ [73]

_____ [74]
Radiologist responsible for data

__-__-____ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

# Interval Scan Advanced MRI

**G1**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Interval Scan for Advanced MRI**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# INTERVAL SCAN

**Instructions:** The advanced MRI imaging and reports are reviewed and the form is completed by the study Radiologist for any interval scan performed. The form is completed when a scan is performed outside of the protocol defined timepoints. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as mm/dd/yyyy. All responses are required unless otherwise noted.

## General Imaging Information

**1. What is the reason for the interval scan?** [97]
- O Rescheduled exam
- O Routine follow-up
- O Other, Specify _____ [98]

**1a.** Reader ID |__|__|__|__|__|__|__| [4]

**1b.** Is the image quality sufficient for analysis? [5]
- O No
- O Yes

**1c.** Was the scanner used for this exam the same as at baseline? [6]
- O No
- O Yes

**2. Date of advanced MRI:** _____-_____-_____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]
- O No
- O Yes

**2b.** Was T-1 weighted post-contrast imaging performed? [9]
- O No
- O Yes

**2c.** Was T2 weighted imaging performed? [10]
- O No
- O Yes

**2d.** Was FLAIR imaging performed? [11]
- O No
- O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]
- O No
- O Yes

**2f.** Was DCE imaging performed? [13]
- O No
- O Yes

**2g.** Was DSC imaging performed? [14]
- O No
- O Yes

**2h.** Was MRS/MRSI imaging performed? [15]
- O No
- O Yes

**3. Patient weight** (measured on day of scan) [16]
|__|__|__|.|__| **kg**

**4. Time of injection** (military time) |__|__|:|__|__| [17]

**5. Contrast administration dose** |__|__|.|__|__| **mmol/kg** [18]

**6. Rate of injection** |__|__|.|__|__| **cc/sec** [19]

**7. Volume of contrast injection** |__|__|.|__|__| **cc** [20]

**8. Volume of saline injection** |__|__|.|__|__| **cc** [21]

**9. Was second injection performed?** [22]
- O No (skip to Q10)
- O Yes

**9a. Time of second injection** [23]
(military time) |__|__|:|__|__|

**G1**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Interval Scan for Advanced MRI**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# INTERVAL SCAN

**9b.** Contrast administration dose of second injection *(skip if second injection not performed)*
___.___ mmol/kg [24]

**9c.** Rate of second injection ___.___ cc/sec
*(skip if second injection not performed)* [25]

**9d.** Volume of second contrast injection ___.___ cc
*(skip if second injection not performed)* [26]

**9e.** Volume of second saline injection ___.___ cc
*(skip if second injection not performed)* [27]

**10. Brand of contrast agent injected** *(check only one)* [28]

O Magnevist
O Omniscan
O ProHance
O OptiMark
O Other, specify _____ [29]

**11. Scan start time (military time)** __:__ [30]

**12. Scan stop time (military time)** __:__ [31]

## Advanced Imaging Scans

**13a.** Are lesions present? [32]

O No *(complete Q13g then sign and date form)*
O Yes

**13b.** Series number and slice number used for measurement

**Series Number** _____ [33]

**Slice Number** _____ [34]

**13c.** Largest Cross-sectional Diameter

___.___ mm [35]

**13d.** Largest Perpendicular Diameter

___.___ mm [36]

**13e.** Location Of Primary (check all that apply)

☐ Frontal lobe [37]
☐ Temporal lobe [38]
☐ Parietal lobe [39]
☐ Occipital lobe [40]
☐ Deep (Basal Ganglia/Thalamus) [41]
☐ Cerebellum [42]
☐ Brainstem [43]
☐ Corpus Callosum [44]
☐ Spinal Cord [45]
☐ Other, [46] Specify _____ [47]

**13f.** Lateralization of Tumor [48]

O Right
O Left
O Bilateral

**13g.** Scan Response [49]

O CR
O PR
O Stable
O Progression
O Not able to be assessed; specify reason

_____ [50]

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC, FA, CBV, Ktrans, Other local permeability, and Choline/NAA ratio:**

**14. Series number and slice number used for measurement**

**Series Number** _____ [51] ☐ **N/A** [95]

**Slice Number** _____ [52] ☐ **N/A** [96]

**G1**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Advanced MRI Assessment Form**
**Interval Scan for Advanced MRI**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

## INTERVAL SCAN

**15. Center of enhancing mass (in enhancing area):**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [53] ☐ **N/A** [77]

**Mean FA** ____.____ [54] ☐ **N/A** [78]

**Mean CBV** ____.____ [55] ☐ **N/A** [79]

**Mean Ktrans** ____.____ [56] ☐ **N/A** [80]

**Mean Other local permeability**

____.____ [57] ☐ **N/A** [81]

**Mean Choline/NAA ratio**

____.____ [58] ☐ **N/A** [82]

**16. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [59] ☐ **N/A** [83]

**Mean FA** ____.____ [60] ☐ **N/A** [84]

**Mean CBV** ____.____ [61] ☐ **N/A** [85]

**Mean Ktrans** ____.____ [62] ☐ **N/A** [86]

**Mean Other local permeability**

____.____ [63] ☐ **N/A** [87]

**Mean Choline/NAA ratio**

____.____ [64] ☐ **N/A** [88]

**17. In normal-appearing tissue**

(If not available mark box to indicate ☑ N/A)

**Mean ADC** ____.____ [65] ☐ **N/A** [89]

**Mean FA** ____.____ [66] ☐ **N/A** [90]

**Mean CBV** ____.____ [67] ☐ **N/A** [91]

**Mean Ktrans** ____.____ [68] ☐ **N/A** [92]

**Mean Other local permeability**

____.____ [69] ☐ **N/A** [93]

**Mean Choline/NAA ratio:**

____.____ [70] ☐ **N/A** [94]

**Comments:** _____

_____ [73]

_____ [74]
Radiologist responsible for data

__-__-____ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

# Interval Scan Standard MRI

**B1**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form**
**Interval Scan for Standard MRI**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# Interval Scan

**Instructions:** The MRI imaging and reports are reviewed and the form is completed by the study Radiologist for any interval scan performed. The form is completed when a scan is performed outside of the protocol defined timepoints. 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/6677, 1818 Market Street suite 1600, Philadelphia, PA 19103. All dates are reported as MM/DD/YYYY. All responses are required unless otherwise noted.

## General Imaging Information

**1. What is the reason for the interval scan?** [97]
- O Rescheduled exam
- O Routine follow-up
- O Other, Specify _____ [98]

**1a.** Reader ID ☐☐☐☐☐☐☐ [4]

**1b.** Is the image quality sufficient for analysis? [5]
- O No
- O Yes

**1c.** Was the scanner used for this exam the same as at baseline? [6]
- O No
- O Yes

**2. Date of MRI:** ____-____-____ [7]
*(mm-dd-yyyy)*

**2a.** Was T1 weighted pre-contrast imaging performed? [8]
- O No
- O Yes

**2b.** Was T1 weighted post-contrast imaging performed? [9]
- O No
- O Yes

**2c.** Was T2 weighted imaging performed? [10]
- O No
- O Yes

**2d.** Was FLAIR imaging performed? [11]
- O No
- O Yes

**2e.** Was diffusion-weighted or diffusion tensor imaging performed? [12]
- O No
- O Yes

**3. Patient weight** ☐☐☐.☐ **kg** (measured on day of scan) [16]

**4. Time of injection (military time)** ☐☐:☐☐ [17]

**5. Contrast administration dose** ☐☐.☐☐ **mmol/kg** [18]

**6. Volume of contrast injection** ☐☐.☐☐ **cc** [20]

**7. Brand of contrast agent injected** *(check only one)* [28]
- O Magnevist
- O Omniscan
- O ProHance
- O OptiMark
- O Other, specify _____ [29]

**8. Scan start time (military time)** ☐☐:☐☐ [30]

**9. Scan stop time (military time)** ☐☐:☐☐ [31]

**B1**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form**
**Interval Scan for Standard MRI**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# Interval Scan

## MRI Assessment

**10a.** Are lesions present? [32]

O No (Complete Q10g, then sign and date form)
O Yes

**10b.** Series number and slice number used for measurement

**Series Number** ☐☐☐☐☐ [33]

**Slice Number** ☐☐☐☐☐ [34]

**10c.** Largest Cross-sectional Diameter

☐☐☐.☐ mm [35]

**10d.** Largest Perpendicular Diameter

☐☐☐.☐ mm [36]

**10e.** Location Of Primary
*(mark all that apply with a check; ☐ = 1 not marked; ☐ √ = 2 marked)*

☐ Frontal lobe [37]
☐ Temporal lobe [38]
☐ Parietal lobe [39]
☐ Occipital lobe [40]
☐ Deep (Basal Ganglia/Thalamus) [41]
☐ Cerebellum [42]
☐ Brainstem [43]
☐ Corpus Callosum [44]
☐ Spinal Cord [45]
☐ Other, [46] Specify _____ [47]

**10f.** Lateralization of Tumor [48]

O Right
O Left
O Bilateral

**10g.** Scan Response [49]

O CR
O PR
O Stable
O Progression
O Not able to be assessed; specify reason

_____ [50]

## Measurements

**Use 1cm diameter region of interest in a single slice for the following measurements of ADC and FA:**

**11. Series number and slice number used for measurement**

**Series Number** ☐☐☐☐☐ [51] ☐ **N/A** [83]

**Slice Number** ☐☐☐☐☐ [52] ☐ **N/A** [84]

**12. Center of enhancing mass (in enhancing area):**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ☐☐☐☐☐.☐☐☐☐ [53] ☐ **N/A** [77]

**Mean FA** ☐☐☐☐☐.☐☐☐☐ [54] ☐ **N/A** [78]

**13. Periphery of tumor (in FLAIR/T2 abnormality but outside enhancement)**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ☐☐☐☐☐.☐☐☐☐ [59] ☐ **N/A** [79]

**Mean FA** ☐☐☐☐☐.☐☐☐☐ [60] ☐ **N/A** [80]

**14. In normal appearing tissue**
(If not available mark box to indicate ☑ N/A)

**Mean ADC** ☐☐☐☐☐.☐☐☐☐ [65] ☐ **N/A** [81]

**Mean FA** ☐☐☐☐☐.☐☐☐☐ [66] ☐ **N/A** [82]

**B1**

**ACRIN 6677 / RTOG 0625**

**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**MRI Assessment Form**
**Interval Scan for Standard MRI**

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

ACRIN Study 6677

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

# Interval Scan

**COMMENTS:** _____

_____

_____

_____ [73]

_____ [74]
Radiologist responsible for data

_____-_____-_____ [75]
Date form completed *(mm-dd-yyyy)*

_____ [76]
Person entering data onto the web

# 6677- END OF STUDY FORM

**DS**

**ACRIN 6677 / RTOG 0625**
**Phase II Trial of Bevacizumab with Temozolomide + Irinotecan**
**Off Study Form**

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

ACRIN Study **6677**

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

**Instructions:** For each registered participant, please submit this form within two (2) weeks of study completion or premature discontinuation, including death.

**1. Off Study status:** [1]

- O 1 Protocol specific criteria and follow-up complete (sign and date form)
- O 2 Premature discontinuation (complete Q2 and Q2a)
- O 3 Participant death (skip to Q3 and Q3a)

**2. Date of premature discontinuation:** _____-_____-_____ *(mm/dd/yyyy)* [2]

**2a. Primary reason for premature discontinuation:** *(check only one)* [3]

- O Adverse events/side effect/complications (also specify on the Adverse Event form)
- O Participant explicitly withdraws study consent/authorizations
- O Protocol violation
- O Did not meet baseline criteria
- O Lost to follow-up (unable to obtain contact with the participant during the prescribed protocol intervals)
- O Unsatisfactory therapeutic effect
- O Abnormal laboratory value(s)
- O Investigator decision (specify reason below)
- O Other (specify reason below)

Specify reason: _____ [4]

**3. Date of death** _____-_____-_____ *(mm/dd/yyyy)* [5]

**3a. Cause of death** [6]

- O Disease Progression
- O Other _____ *(specify cause of death)* [7]

**COMMENTS:** _____

_____

_____ [8]

_____ [9]
Signature of person responsible for the data

_____-_____-_____ [10]
Date form completed (mm-dd-yyyy)

_____ [11]
Signature of person entering data onto the web

# 6677- ADDITIONAL FORMS

# AE ACRIN Adverse Event Form

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

ACRIN Study Case #

**PLACE LABEL HERE**

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

All Adverse Events (AEs) and Serious Adverse Events (SAEs) as defined in the protocol require routine reporting via web entry of the AE CRF. In addition, SAEs meeting the criteria for expedited reporting, as specified in the protocol, require (a) telephone report to both NCI (via TRI) and ACRIN within 24 hours of first knowledge of the event, (b) AdEERS report completed and submitted as specified in the protocol, and (c) completed AE case report form with investigator's signature submitted to ACRIN via web and filed in the participant 's chart.

| AE Description [1], [2] | CTCAE Grade | Attribution | | Serious AE? | AdEERS Submitted for SAE | Action Taken (check all that apply) | Outcome | Date of AE Onset and Resolution |
|---|---|---|---|---|---|---|---|---|
| | 1 = Mild<br>2 = Moderate<br>3 = Severe<br>4 = Life threatening or disabling<br>5 = Fatal<br>[4] | 1 = Unrelated<br>2 = Unlikely<br>3 = Possible<br>4 = Probable<br>5 = Definite<br>[5] | 1 = Expected<br>2 = Unexpected<br>[6] | 1 = No<br>2 = Yes<br>[42] | 1 = No<br>2 = Yes<br>[7] | 1 = None [43]<br>2 = Medication therapy [44]<br>3 = Procedure [45]<br>4 = Hospitalization [46]<br>5 = Other [47] | 1 = Recovered<br>2 = Improved<br>3 = Ongoing<br>4 = Death<br>5 = Unknown<br>[9] | (mm-dd-yyyy); check box "on-going" if the AE is on-going at the time of report<br>☑ On-going |
| **AE Short Name CTCAE v3.0** [3] | | | | | | | | Start date: [10]<br>_____ - _____ - _____<br>Resolution date: [11]<br>_____ - _____ - _____<br>☐ On-going [12] |

**Comments**: _____ [37], [38]

**Additional AEs to report?** [39]

O 1 No

O 2 Yes (Please complete an additional AE form)

_____ [40]

**Investigator responsible for data**

_____-_____-_____ [41]

**Date form completed (mm-dd-yyyy)**

PR

**ACRIN 6677**
**Protocol Deviation Form**

**ACRIN Study 6677 Case #**
**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

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

**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 at www.acrin.org; retain the form in the case study file.

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

- ☐ 1 Inclusion/exclusion criteria not met at time of registration/randomization
- ☐ 2 Patient consented to advanced imaging but standard imaging performed
- ☐ 3 Standard imaging-related deviation *(complete Q1a)*
- ☐ 4 Advanced imaging-related deviation *(complete Q1b)*
- ☐ 88 Other, specify: _____ [2]

**1a. Image Deviation:** *(Select only one)*

**i. Standard MR Imaging Deviation** *(select only one)* [3]

- ☐ 1 Standard MRI scan not performed according to protocol specific intervals
- ☐ 2 Standard MRI interpretation guidelines not followed
- ☐ 3 Standard MRI scan performed at a non-ACRIN qualified institution
- ☐ 4 Standard MRI scan performed on a non-ACRIN qualified scanner
- ☐ 5 Standard MRI scan performed on a different scanner from the Baseline MR Imaging
- ☐ 6 Standard MR images lost or unavailable
- ☐ 7 Standard MR imaging incomplete
- ☐ 8 Standard MRI scan procedure/parameters incorrect/outside acceptable limits
- ☐ 88 Other, specify _____ [4]

**1b. ii. Advanced MR Imaging Deviation:** *(Select only one)* [5]

- ☐ 1 Advanced MRI scan not performed according to protocol specific intervals
- ☐ 2 Advanced MRI interpretation guidelines not followed
- ☐ 3 Advanced MRI scan performed at a non-ACRIN qualified institution
- ☐ 4 Advanced MRI scan performed on a non-ACRIN qualified scanner
- ☐ 5 Advanced MRI scan performed on a different scanner from the Baseline MR Imaging
- ☐ 6 Advanced MR images lost or unavailable
- ☐ 7 Advanced MR imaging incomplete
- ☐ 8 Advanced MRI scan procedure/parameters incorrect/outside acceptable limits
- ☐ 9 MultiHance contrast agent used
- ☐ 88 Other, specify _____ [6]

PR

**ACRIN 6677**
**Protocol Deviation Form**

**ACRIN Study 6677 Case #**

**PLACE LABEL HERE**

**Institution** _____ **Institution No.** _____

**Participant Initials** _____ **Case No.** _____

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

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

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

**4. Describe the protocol deviation:**

_____ **[9]**

_____ **[10]**

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

_____ **[11]**

_____ **[12]**

**6. Please provide the time point this Study Deviation applies to:** **[13]**

☐ **1.** Pre-study ☐ **4.** Week 16 ☐ **7.** Week 40 ☐ **10.** Week 64 ☐ **13.** Week 88 ☐ **16.** Interim (G1/B1) visit

☐ **2.** Week 2 ☐ **5.** Week 24 ☐ **8.** Week 48 ☐ **11.** Week 72 ☐ **14.** Week 96

☐ **3.** Week 8 ☐ **6.** Week 32 ☐ **9.** Week 56 ☐ **12.** Week 80 ☐ **15.** Final Off-study

_____ **[14]**
**Person responsible for data (RA, study staff)**

____-____-**20**____ *(mm-dd-yyyy)* **[15]**
**Date Form Completed**

_____ **[16]**
**Investigator Signature**