Imaging Forms for Protocol 0825/6686

MRI Assessment

V1  Advanced MRI Local Technical Assessment ............................... 12-14-09

End of Study

DS  End of Study ................................................................. 04-07-10

Additional Forms

AE  Adverse Events. ................................................................. 03-04-10
PR  Protocol Deviation. ............................................................ 09-01-10

Enter the imaging data through the Data Center on the ACRIN website. All data should be entered within two weeks of the MRI.

Any questions related to these forms should be directed to:

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

1. Clinical trial timepoint
   - Baseline
   - Week 3
   - Week 3 + 1 day
   - Week 10

2. Was advanced MRI imaging performed at this visit?
   - No (Complete Q2a then initial and date form)
   - Yes

2a. Reason imaging not performed (check only one)
   - Scheduling Problem
   - Equipment failure
   - Patient refusal
   - Medical contraindication
   - Injection site complications
   - Claustrophobia
   - Only standard imaging performed
   - Other, specify ________________

3. Has the scanner used for this study been qualified by ACRIN?
   - No, specify reason ________________
   - Yes

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

5. Subject weight (measured day of scan)
   ___ ___ ___ ___ : ___ KG
   Unknown

6. Subject height (measured day of scan)
   ___ ___ ___ ___ CM
   Unknown

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

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

First Injection (DCE-MRI)

9. Brand of contrast agent injected (check only one)
   - Magnevist
   - Omniscan
   - ProHance
   - OptiMark
   - MultiHance*
   - Vasovist*
   - Other, specify ________________

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

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

11. Rate of injection ___ ___ ___ cc/sec

12. Volume of contrast injection ___ ___ ___ cc

13. Volume of saline injection ___ ___ ___ cc

Second Injection (DSC-MRI)

14. Was second injection performed?
   - No (Initial and date form)
   - Yes

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

16. Rate of injection ___ ___ ___ cc/sec

17. Volume of contrast injection ___ ___ ___ cc

18. Volume of saline injection ___ ___ ___ cc

COMMENTS:

__________________________
Initials of person responsible for data

__________________________
Date form completed (mm-dd-yyyy)

Version 1.0  6686  V1  12-14-09  1 of 1
1. Provide reason for study disposition by selecting one of the following:

   O 1  Protocol defined follow-up completed

   O 2  Participant lost to follow-up

   O 3  Participant refused follow-up / withdrew

   O 4  Death (specify date and cause below)

   Date of death: __________/________/________ (mm/dd/yyyy)

   Cause of death:

   O 1  Disease Progression

   O 8  Other, specify _________________________________

   O 5  Adverse Event / Side Effects / Complications

   O 6  Protocol violation: (check all that apply)

   □  Did not meet eligibility

   □  Technical problems

   □  Related to study visits

   □  Related to imaging

   □  Related to randomization

   □  Other (specify below)

   O 7  Disease progression

   O 8  Study terminated by sponsor

   O 8  Other (specify reason below)

   Specify reason: _________________________________

2. Date of disposition: __________/________/________ (mm/dd/yyyy)

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

   O 1  No

   O 2  Yes

Comments: ____________________________________________________________

__________________________  _________________________
Initials of person completing the form  Date form completed (mm-dd-yyyy)

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

Investigator's signature ________________________________
ACRIN Adverse Event Form  
ACRIN Study 6686

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

### AE Description

#### AE Short Name (online look-up)

<table>
<thead>
<tr>
<th>Grade</th>
<th>Attribution</th>
<th>Expectedness</th>
<th>Serious AE?</th>
<th>Expedited Report Submitted</th>
<th>Action Taken (mark X all that apply)</th>
<th>Outcome</th>
<th>Date of AE Onset and Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>None [43]</td>
<td>Recovered</td>
<td>(mm-dd-yyyy); mark X the box &quot;ongoing&quot; if the AE is ongoing at the time of report</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Medication therapy [44]</td>
<td>Improved</td>
<td>Start date: [10]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Hospitalization [46]</td>
<td>Death</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Other [47]</td>
<td>Unknown</td>
<td></td>
</tr>
</tbody>
</table>

- O Mild
- O Moderate
- O Severe
- O Life threatening or disabling
- O Fatal
- O Unrelated
- O Unlikely
- O Possible
- O Probable
- O Definite
- O Expected
- O Unexpected
- O No
- O Yes
- O None
- O Medication therapy
- O Procedure
- O Hospitalization
- O Other

#### Comments:

- O Additional AEs to report? [39]
- O Was the AE assessed, reviewed and signed by the investigator? [40]
- O Date form completed (mm-dd-yyyy) [41]
- O Investigator’s initials [50]

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ACRIN 6686
Phase III Trial of Bevacizumab with Temozaolomide vs. Chemoradiation with Temozaolomide Advanced MRI

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

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

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

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

1b. Imaging affected (Select only one) [5]
   - 1 DCE
   - 2 DSC
   - 88 Other, specify ___________________________ [6]

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

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

4. Describe the protocol variation:
   ____________________________________________ [9]
   ____________________________________________ [10]

5. What was done to rectify the situation and/or prevent future occurrence:
   ____________________________________________ [11]
   ____________________________________________ [12]
ACRIN 6686
Phase III Trial of Bevacizumab with Temozaolomide vs. Chemoradiation with Temozaolomide Advanced MRI

6. At what time point did this study deviation occur? [13]
   - Baseline
   - Week 3
   - Week 3 + 1 day
   - Week 10

7. Was variation form signed by investigator? [14]
   - No
   - Yes

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Initials of person responsible for data (RA, study staff) [15]

Date Form Completed [16]

Investigator's signature ____________________________ (for external use only)