ACRIN 6671 M1 FORM COMPLETION INSTRUCTIONS

Visit 2: MRI Scan

M1: MRI Lymph Node Evaluation Form

The M1 Form is to be completed by the ACRIN MRI Radiologist at the GOG/ACRIN site for the MRI Lymph Node Evaluation. This form must be completed while blinded to the results of other imaging examinations and clinical data. The MRI images will be transmitted to ACRIN. The data is submitted via the ACRIN website. Only submit the paper form for revisions, corrections or in the event that the ACRIN website is inaccessible. All available dates should be reported as mm-dd-yyyy. Online logic prevents the entry of future dates. Code all questions unless otherwise specified. Do not leave mandatory questions blank. The original paper CRF can serve as the source document for the interpretation and should be retained in the study file. Please note that instructions are not listed for each question. These instructions are for questions that require additional clarification. If a question requires further clarification, please contact ACRIN headquarters at 215-574-3150 and ask for the ACRIN 6671 Data Manager.

1. Was MRI performed?

- If "No" complete question 1a, then sign and date form.
- If "Yes" skip Q1a and complete remaining questions.

3. Date of MRI interpretation

Record the date that the MRI was interpreted by MRI qualified Radiologist.

4. Reader ID:

Record the 7 alphanumeric ACRIN-designated Reader ID.

5. T1 Weighted Sequence

- If the image quality is "adequate" then skip to Q6.
- If the image quality is "suboptimal" then complete Q5a.

6. T2 Weighted Sequence

- If the image quality is "adequate" then skip to Q7.
- If the image quality is "suboptimal" then complete Q6a.

7. T2* Weighted Sequence

- If the image quality is "adequate" then skip to Q8.
- If the image quality is "suboptimal" then complete Q7a.

9. Size of Tumor

- <u>Anterior/Posterior</u>: accepts value between 10–100 mm. A decimal point is required. If data is out of this range, contact data management.
- <u>Transverse</u>: accepts value between 10–100 mm. A decimal point is required. If data is out of this range, contact data management.
- <u>Cephalocaudal</u>: accepts value between 10–100 mm. A decimal point is required. If data is out of this range, contact data management.

10. Maximum depth of stromal invasion

The range for this response is 0-50 mm.

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Signature of person responsible for data:

This is only required if the MRI was not performed. Legible signature/name of the radiologist responsible for collating/reviewing the data and ensuring completion of the CRF (paper or web). If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the radiologist responsible for the data

Date form completed:

Record the date the original CRF, whether paper or web, was completed. If completing a paper CRF this refers to the date the data was originally recorded on the paper CRF; the date/time of web entry is automatically recorded by the database. If completing the web CRF only, without completing a paper CRF, this refers to the date the data was originally recorded in the web module.

Signature of person entering data onto web:

Record the signature/name of the staff member submitting the data online. If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member entering the data onto the web.