SUMMARY OF CHANGES

ACRIN 6659: MR Imaging and MR Spectroscopic Imaging of Prostate Cancer Prior to Radical Prostatectomy: A Prospective Multi-Institutional Clinicopathological Study

Amendment #5        July 16, 2003

Index
In the heading for 7.0, “and Randomization” has been deleted.

In the heading for 10.0, “Pathology and” has been added.

The heading of 14.0 has been changed from “Auditing” to “Institutional Audits.”

Appendix VIII has been added to the index.

8.6.2
“Executive Committee” has been changed to “Steering Committee.”

10.1
This section previously read as follows:

Digitally generated MR images and spectral arrays will be transmitted to the ACRIN Image Management Center (IMC) via FTP directly to the image archive. The FTP site is located at ftp://xray.acrin.org or ftp://206.137.103.34. For each transmission a new folder for each institution and sub-folders for each corresponding exam must be created. Images are then transferred into those folders. An e-mail verifying the transfer and its contents including the name and number of exams as well as image count for each will be sent to both alevering@phila.acr.org and rwelsh@phila.acr.org. Transmission will be verified by examining the folders to make certain that all the images were received. If you encounter any problems or need assistance getting started with the steps required to transmit the required digital MRS/I studies to the ACRIN image archive, you should contact the Image Management Center at ACRIN (Anthony Levering, 215-574-3244, or Rex Welsh, 215-574-3214).

It now reads,
All images for this protocol are requested to be provided in digital format. ACRIN has developed software that allows for electronic transmission to the DMC image archive of images that have been scrubbed of all patient identifiers. Individual PC computers with this software installed will be supplied to each participating site. ACRIN will be contacting each site individually to determine their readiness and ability to work with this system. If you have preliminary questions, you may contact either Rex Welsh or Fraser Wilton (215-574-3215) for information about this system. Once readiness has
been determined, imaging personnel from ACRIN will coordinate the shipment and installation of the PC computers and train all operating staff on use of the system.

10.2.1
At the end of the first sentence in the “standard blocks” section, the following has been added: “provided that the entire prostate and lower portions of the seminal vesicles are submitted for microscopic examination, by a method which allows for precise reconstruction for mapping purposes.” At the beginning of the next sentence, “In that way,” has been added, and the word “will” has been inserted between “blocks” and “allow.”

10.2.2
The first sentences in this section have been changed. Previously, they read, “All pathology specimens will be reviewed, and signed out at the surgical institution. After this review, a duplicate set of all slides will be sent for a central review by ACRIN.” They now read, “All pathology slides will be cut in duplicate. The specimens will be reviewed and signed out at the surgical institution. Following case sign-out, the duplicate set of all slides will be sent for a central review by ACRIN.” In the address, Dr. Wheeler’s middle initial (M.) has been added.

11.1
In the second sentence, “in combination with” has been changed to “and.”

13.6.1
The Biomedical Imaging Program (BIP) has been changed to the Cancer Imaging Program (CIP).

13.7.2
The director’s name has been deleted. Biomedical Imaging Program has been changed to Cancer Imaging Program.

14.1
The Biomedical Imaging Program (BIP) has been changed to the Cancer Imaging Program (CIP).

Appendix II
“Eligibility Checklist” has been added to the heading.

The code table for “Race” (#10) has been replaced by check boxes as follows:

10. Race (check all that apply):
   - American Indian or Alaskan Native
   - Asian
   - Black or African American
   - Native Hawaiian or other Pacific Islander
   - White
   - Unknown
Question #16 has changed from “Registration Date” to “Calendar base date.”

Question #17 (“Registration Date”) has been added.

Question # 18 (“Other country of residence, specify”) has been added.

Appendix VIII
This appendix, detailing the procedure by which sites become certified, has been added:

**MRS/Imaging Test Case Submission and Approval Process**

Each participating site will be required to submit and have approved the 6659 study-specific MR Spectroscopy Imaging for three test participants prior to enrolling its first study participant. Notification of approval will be disseminated by ACRIN Headquarters upon completion of the case review. Your site will not be able to accrue to the 6659 protocol without this prior approval and notification.

Patients whose images will be sent as test cases do not need to sign the ACRIN 6659 study-specific consent form (Appendix I to the protocol) because they will not be participating in this study. Those patients will, however, need to sign a Health Insurance Portability and Accountability Act (HIPAA) authorization that gives permission for their images to be sent to ACRIN. ACRIN does not monitor HIPAA compliance; any HIPAA questions should be directed to the local Institutional Review Board (IRB).

The complete MRS/imaging studies will be transmitted to the ACRIN image server via the installed ACRIN transfer computer. (See Section 10.1 of the protocol for the image transmission procedure.) In the event the ACRIN transfer computer is not installed at your site, the MRS/I studies can be archived onto a CD that is PC readable. The images must be in valid DICOM 3.0 format. They should be sent to the following address:

**ACRIN Study 6659 Image Archive**
1101 Market Street, 14th Floor
Philadelphia, PA 19107

**URGENT: Image ACRIN study 6659 test cases enclosed**

It is required that the naming convention for each test study be consistent with the standard naming convention for actual study participants. (See Section 10.1.1.) In an effort to maintain consistency in naming the test MRS/imaging cases, the patient name tag will be replaced with the SITE Test#^Institution ID (ex: test1^4444, test2^4444 etc.) and the patient ID tag with the Site test number again (ex: test1^4444, test2^4444 etc.); the study number should be put on the other patient ID tag (6659). Once received at ACRIN, the imaging studies will be reviewed by the Spectroscopy Advisor, John Kurhanewicz, PhD (john.kurhanewicz@mrsc.ucsf.edu). Any changes that may be required to the acquisition technical parameters or the anatomic coverage will be
communicated by Dr. Kurhanewicz to each site via electronic mail. The anticipated turnaround time for approval of each case is 5-7 working days.

Please feel free to contact Anthony Levering (alevering@phila.acr.org; 215-574-3244) or Sharlene Snowdon (ssnowdon@phila.acr.org; 215-717-2753) with questions you may have regarding the test case submission and approval process.

For questions regarding image transfer and ACRIN computer issues, contact either Rex Welsh (rwellsh@phila.acr.org, 215-574-3215) or Fraser Wilton (f wilton@phila.acr.org).
SUMMARY OF CHANGES

ACRIN 6659: MR Imaging and MR Spectroscopic Imaging of Prostate Cancer Prior to Radical Prostatectomy: A Prospective Multi-Institutional Clinicopathological Study

January 31, 2003

Title Page
Dr. Weinreb’s contact information has changed. The address is as follows:

Jeffrey C. Weinreb, MD
Chief of MRI, Professor of Radiology
Yale University School of Medicine
Department of Radiology
333 Cedar St., Room MRC 147
New Haven, CT  06520
Phone: 203-785-5913
Fax: 203-785-3061
E-mail: jeffrey.weinreb@yale.edu

The zip code for Dr. Wheeler, the pathology advisor, should be 77030, not 77030-2681.

Index
Two new sections (13.0 and 14.0) have been added to the index, and page numbers have been changed. Appendices VI and VII have been added.

Eligibility
The following has been added to the end of the list of eligibility criteria: “Encourage retrieval of any outside biopsy reports and slides (medical release form with signature).”

5.1.1
Page 8: After the second sentence, a sentence has been added: “Official report of biopsy from outside site.”

5.1.2
Page 8: The phrase “Sites must submit” was added to the beginning of the sentence.

5.2.3
Page 8: At the end of the sentence, the words “or have Crohn’s disease” have been added.

5.2.5
Page 8: The list of exclusion criteria has been expanded to include “rectal surgery”; “PC SPES therapy” has been replaced by “complementary alternative medicine.”
7.1.1
Page 9: In the second sentence, “the link for new patient registrations” has been changed to “the link for data center login/ACRIN protocols.”

8.7-8.8
These sections have been deleted because they have been replaced by sections 13 and 14.

9.1
Page 13: In the data collection table, the S5 has been changed from a “form” to a “report.” In the PC column, the second “2 weeks post surgery” has been deleted. A row has been added to the middle: “PI: Pathology Report (Biopsy), At time of registration.” A row at the end has been added: “QA Form: MRSI Quality Assurance, 1 week post imaging.”

10.1
Page 13: In the first sentence, “MR” has been added before “images”, “scanned film diagnostic images” has been deleted, “can” has been changed to “will”, “Data” has been changed to “Image”, and “DMC” has been changed to “IMC.” In the fifth sentence, the e-mail address amurray@phila.acr.org has been changed to rwelsh@phila.acr.org. A sentence has been added to the end of the section: “If you encounter any problems or need assistance getting started with the steps required to transmit the required digital MRS/I studies to the ACRIN image archive, you should contact the Image Management Center at ACRIN (Anthony Levering, 215-574-3244, or Rex Welsh, 215-574-3214).”

10.1.1
Page 13: Three sentences have been added to the end of this section: “The header recorded on DICOM formatted image data, which often contains information identifying the patient by name, will be scrubbed before the image is transferred. This involves replacing the patient name tag with the ACRIN Case#^Institution ID, the patient ID tag with the ACRIN case number again; the study number should be put on the other patient ID tag. This can be done using either software at the institution or software available from the ACRIN IMC (attention Rex Welsh, 215-574-3125).” The remainder of this section has been deleted.

10.1.2 and 10.1.3
These sections have been deleted, and the next section has been renumbered accordingly.

10.1.2 (formerly 10.1.4)
Page 13: “DMC” has been changed to “IMC”; “either” and “or CDROM where appropriate” have been deleted.

10.2.2
Page 14: The last four digits of Dr. Wheeler’s ZIP code have been deleted.
10.2.3
Page 14: The ACRIN data management fax number has been changed to 215-717-0936.

10.2.4
Page 14: In the last sentence, the word “Center” has been deleted in the first instance, and the phrase “in turn” has been deleted.

11.1.2.3
Page 15: In the table, in the last column for TE (msec), the number 130 has been inserted. In the last column for Field of View (FOV), the number has been changed from 56 to 55. In the last column for spectral width, the number has been changed from 1250 Hz to 1000 Hz. In the last column for Notes, “5 Hz” has been changed to “≤ 12 Hz”; spatial resolution has been changed from “.24 cm³ to .54 cm³” to “.3 cm³”

11.2
Page 16: The following sentence has been deleted: “After a whole-voxel water and lipid-suppressed spectrum is acquired and stored, a 3D MRSI data set will be acquired using a PRESS (Point-Resolved Spectroscopy) technique employing two phase compensating spectra/spatial pulses in place of the conventional 180° pulses.”

The eighth sentence used to read, “The selected volume will be over-prescribed by 30% and VSS pulses will be automatically placed at the original boundaries of the selected volume.” It has been split into two sentences that now read, “The selected volume will be over-prescribed by 10% (AP) and 30% (RL, SI). VSS pulses will be automatically placed at the original boundaries of the selected volume.” A few sentences later, the equation “FOV = 120 x 60 x 60 mm³” has been changed to “FOV = 110 x 55 x 55.”

11.2.1
This section has been deleted because it duplicates information in 11.1.2.3.

11.3
Page 16: The former section 11.3 has been deleted. The following has been added:

*MRSI quality will be assured in several ways.*

*Prior to the start of the trial: 1) All sites participating in the trial will receive a quality assurance prostate phantom with the GE prostate spectroscopy package. 2) Technologists at all participating sites will be trained in acquiring prostate spectral data from both the phantom and the patient. 3) Each site will have to prove that it can acquire good quality prostate spectral data. To accomplish this, all sites will acquire and submit one set of phantom data using the prostate phantom. Next, data sets from three test patients will be acquired and submitted. The MRI and MRSI data from the phantom and the 3 patients will be reviewed centrally,*
and each site will receive feedback regarding the test cases before randomizing the first study participant.

**During the course of the trial:** 1) All sites will perform QA phantom studies within one week of patient studies to assure the MR scanner is functioning properly for reproducible data acquisition. To accomplish this, PROBE single voxel spectroscopy package with body excite and 5-inch GE surface coil receive will be used to acquire spectra from the GE Brain spectroscopy phantom. 2) The technologists will run a simple protocol similar to the QA protocol used for MRI (see the QA protocol in Appendix VI) and will record a series of parameters including shim value, spectrometer gain, water line-width, and metabolite signal to noise ratios (see QA form).

**11.4.1**
Page 17: After the fourth sentence, the following has been added: “The readers will first interpret MRI alone by scoring each sextant on the degree of suspicion scale and will then interpret MRSI under the same scoring scheme.” That sentence has been deleted from 12.3. Another sentence has been added following: “For each sextant, both the estimated probability of foci presence and the category of presence (defined on the standard 5-point scale) will be recorded. Note that both measures will be reported, first for the MRI alone and then for the MRI/MRSI combined.”

**12.4.1**
Page 19: In the first paragraph, one sentence has been modified. It used to read, “However, in order to take into account the trade-off between sensitivity and specificity, the full range of assessments on the 5-point ordinal scale will be analyzed using ROC methodology”; it now reads, “In order to take into account the trade-off between sensitivity and specificity, the full range of assessments made on the 5-point ordinal scale and on the 0-100% probability scale will be analyzed using ROC methodology.”

The following sentence has been inserted in the middle of the first paragraph: “In addition, use of the quasi-continuous probability scale (reader-reported probability of malignancy) will be used to obtain nonparametric estimates of the area under the ROC curve.”

**13.0 and 14.0 (new sections)**
Pages 22-25: The following two sections have been added:

**13.0 ADVERSE EVENT REPORTING**

**13.1 Definition of Adverse Event**

An Adverse Event (AE) is any untoward medical occurrence in a patient that does not necessarily have a causal relationship with the study intervention. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease
temporally associated with the use of a medical treatment or procedure regardless of whether it is considered related to the medical treatment or procedure (attribution of unrelated, unlikely, possible, probable, or definite).

13.2 Definition of Serious Adverse Effect

Serious Adverse Event (SAE) is defined as any untoward medical occurrence that:
- Results in death or is life-threatening (at the time of the event) or
- Requires inpatient hospitalization or prolongation of an existing hospitalization or
- Results in persistent or significant disability or incapacity.

13.3 Adverse Event Grading

Grade is used to denote the severity of the adverse event. An AE is graded using the following categories (provided the term does NOT appear in the current version of the Common Toxicity Criteria [CTC]):
- 0 – Within normal limits
- 1 – Mild
- 2 – Moderate
- 3 – Severe
- 4 – Life-threatening or disabling
- 5 – Fatal

(For terms listed in the CTC, the grade is still recorded as 1, 2, 3, 4, or 5; however, the definition of the various grades will be specific to the term being used.)

13.4 Expected Adverse Events from MRI

- Claustrophobia in MRI magnet
- “Warming” sensation from endorectal coil
- Discomfort from rectal coil insertion

13.5 Reporting of Adverse Events

Prompt reporting of adverse events is the responsibility of each investigator, clinical research associate, and nurse engaged in clinical research. Please refer to the ACRIN Adverse Event Reporting Manual for specific details about what to report and when. Anyone uncertain about whether a particular adverse event should be reported should contact the ACRIN headquarters at 215-574-3150 for assistance. Any event that is judged to be NOT related to the treatment or procedure should NOT be reported as an adverse event. However, an adverse event report should be submitted if there is a reasonable suspicion of the medical treatment or imaging procedure effect.

13.6 When to Report

13.6.1 You must use expedited event reporting to within 10 working days for all Grade 5 events occurring within 30 days of the study intervention, regardless of attribution and regardless of whether the event was expected or unexpected. You must use expedited event reporting within 10 working days for Grade 4 unexpected events occurring within 30 days of the study.
intervention, regardless of attribution. These reports should be sent to ACRIN, NCI’s Biomedical Imaging Program (BIP), and the local Institutional Review Board (IRB).

13.6.2 All fatal (Grade 5) adverse events should also be reported by telephone to NCI and ACRIN within 24 hours of the event.

13.6.3 Expedited adverse event reporting is NOT required for expected events of grades 1-4 or unexpected-indirect adverse events of any grade.

13.6.4 All expedited reports should be reported within ten (10) working days of knowledge of the event. All fatal adverse events should also be reported by telephone to the NCI and to ACRIN within 24 hours of knowledge of the event.

### 13.7 How to Report

13.7.1 An expedited adverse event report requires submission to the NCI-BIP and ACRIN using the paper templates “Adverse Event Expedited Report—Single Agent” or “Adverse Event Expedited Report—Multiple Agents,” available on the CTEP home page, [http://ctep.info.nih.gov](http://ctep.info.nih.gov). Protocols involving only imaging procedures must be submitted using a paper version. Investigators following those protocols should omit the Course Information section and the Protocol Agent section, even though the template indicates those as mandatory. (Do not try to send the form via the web site; it will not accept a form without those fields filled in.)

13.7.2 Completed expedited reports should be sent to:

**NCI**

*Barbara A. Galen, MSN, CRNP, Program Director*

Re: Adverse Event Report

Biomedical Imaging Program

6130 Executive Blvd., MSC 7412

Bethesda, MD 20892-7412

To make a telephone report, contact NCI at (301) 496-9531, available 24-hours a day (recorder after hours from 5 PM to 9 AM ET).

13.7.3 A copy of all expedited adverse event reports should be sent to ACRIN by fax at (215)-717-0936. All fatal adverse events should be reported by telephone within 24 hours of the event. To make a telephone report to ACRIN, call (215)-717-4763, available 24 hours a day (recorder after hours from 5 PM to 8 AM ET).

13.7.4 All expedited adverse event reports should be sent to your local Institutional Review Board (IRB). Adverse events not requiring expedited reporting are normally reported to your local IRB in an annual report.

### 14.0 INSTITUTIONAL AUDITS

14.1 Institutional on-site audits will be completed within 18 months of a site’s enrolling its first ACRIN participant. Subsequent audits will be scheduled per the outcome of the initial audit. Auditors will follow procedures
established by the Biomedical Imaging Program (BIP) of the NCI. Instructions for preparing for the audit will be sent to sites in advance of the audit date. With these instructions, the auditors will specify which case records will be reviewed during the audit. Auditors will review on-site records against the reviewed data, and they will record their findings on specially prepared questionnaires. Major discrepancies will be forwarded to the appropriate oversight body within ACRIN. IRB procedures, approvals, and consent forms will be also reviewed at the audit.

14.2 To help sites prepare for audits and assure that clinical RAs maintain records appropriately, the BDMC will offer training. This training will cover all aspects of data collection, but will include special instructions for finding and filing the kinds of source documentation needed to verify the accuracy of submitted data for this trial.

14.3 **Source documentation:** Data elements that are expected to be extracted from the medical record (patient history, official clinical interpretations of images, pathology or surgery results) and recorded on the case report forms (CRFs) will be audited against the appropriate component of the medical record. Data elements gathered from signed patient questionnaires may be documented on the CRF. The image interpretation data beyond that documented in the radiology report may be recorded on the CRF and is accepted as source documentation if signed by the MD. At the time of audit, the auditor will verify the occurrence of the imaging examination, the reader, and the date on which the exam took place from the medical record. Any use of an approved CRF as source documentation requires that the CRF be signed and dated and refer to the source of the information (patient questionnaire, MR, etc.). Section 9.7 includes a listing of study-specific forms and the source documentation that will be accepted at the time of the audit. Any use of CRFs as source documentation where it is designated the information will be audited against the medical record will be considered a discrepancy.

14.4 **Institutional Review Board:** Sites must have on hand documentation of IRB approval prior to subject registration, including a copy of IRB approval of initial application, a copy of IRB approval of modifications, and copies of annual renewal(s).

14.5 **Equipment Safety or Service Reports:**

**MR Scanner:** Obtain copies of MRI Preventive Maintenance Reports for the previous 18 months or the duration of the study (whichever is less) for review at the time of the audit. Preventive maintenance is usually performed at least once every 3 months by the scanner manufacturer’s service engineer, and reports may be maintained by the facility or the manufacturer. Sites must have MR Preventive Maintenance Reports documenting quarterly service.

14.6 **Research Records:** Maintain source documentation for each case that substantiates the data reported to ACRIN. Source documentation includes the following:
- hospital chart or legible copies
- clinic chart or legible copies
- pathology reports or legible copies
- MRI reports or legible copies
- MRSI reports or legible copies
- forms signed and dated by the subject
- ACRIN case report forms signed by the physician
- worksheets signed by the physician which are used by research staff to submit the data on case report form(s)
- verification of receipt of submitted case report forms (mailed or emailed from ACRIN to site)

Source documentation must verify the eligibility criteria and data submitted on all case reporting forms. If an item is not mentioned (e.g., history and physical with no mention of a psychological condition) it will be assumed it is not present.

It is suggested that the research record for each case contain copies of the source documentation for the data reported to ACRIN. Copy the source documentation as you abstract the data from the primary record. This will prevent a discrepancy and inability to document the data reported when reviewed by auditors.

**14.7 AUDIT 6659 Source Documentation**

<table>
<thead>
<tr>
<th>AO-Case Registration Form</th>
<th>Printed copy, CRF signed and dated by RA</th>
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<tbody>
<tr>
<td>11-Initial Clinical Evaluation Form</td>
<td>Lab Report (PSA specifically) History &amp; Physical Pathology Report (biopsy)</td>
</tr>
<tr>
<td>M3-MRI/MRSI Imaging Technical Form</td>
<td>MRI Report MRSI Report</td>
</tr>
<tr>
<td>PC-Pathology Submission Form (slides)</td>
<td>Pathology Report (surgical)</td>
</tr>
<tr>
<td>P4-Central Pathology Evaluation Form</td>
<td>Interpretation of Pathology Report from Central Reader</td>
</tr>
<tr>
<td>QA-MRSI Quality Assurance Form</td>
<td>Printed copy, CRF signed and dated by reader.</td>
</tr>
</tbody>
</table>

Source documentation includes signature and date of appropriate persons

**References**

Page 28: The original reference #50 has been deleted because the sentence citing it was deleted from the text.
Appendix I: Sample Consent
Page 30: Under the heading “What is involved in this study?”, the following has been deleted: “You will be asked to clear your bowels with a Fleet enema 1-3 hours before the MRI and MRSI. The enema is used to obtain the best quality image (scan) possible.” Those sentences have been replaced with the following: “You will be administered a Fleet enema 1-3 hours before the MRI or MRSI. The enema is used to clear out your bowels in order to obtain the best quality image (scan).

Page 30: Under the heading “MRI (Magnetic Resonance Imaging)”, the phrase “empty your bowels” has been changed to “clear your bowels with a Fleet enema.”

Page 30: Under the heading “MRSI (Magnetic Resonance Spectroscopic Imaging)”, the following has been added to the end of the section: “Additional studies may be done using the data and images we collect as part of this research project. The data and images will reside at the ACRIN data center as part of the overall ACRIN database and image archive.”

Page 30: Under the heading “Pathology,” the following has been deleted: “office for review and research investigation associated with this protocol. Additional studies may be done using the data and images we collect as part of this research project. The data and images will reside at the ACRIN data center as part of the overall ACRIN database and image archive.” The final sentence of the section now reads, “This tissue will be sent to a central storage facility located at Methodist Hospital in Houston, Texas.”

Appendix II: Tissue Banking Consent
Page 35: In the second paragraph, the phrase “and may be used in research to learn more about cancer and other diseases” has been deleted. That sentence now reads, “If you agree, this tissue will be kept at a central storage facility at Methodist Hospital in Houston, Texas under the direction of Dr. Thomas Wheeler.” “xyz” has been changed to “Methodist Hospital.”

Appendix III: Eligibility Checklist
Pages 37-38: The wording and numbering of the items have been changed. It now reads:

APPENDIX III

ACRIN  6659
Institution #______________
6659 Case #______________ (to be provided upon registration)
________(Y)  1. Biopsy proven adenocarcinoma of the prostate.

___/____/____  2. Date of prostate biopsy
3. Written documentation from the Urologist confirming the scheduled date of the radical prostatectomy at the study site is within 6 months of MRI/MRSI.

4. Projected date of surgery (scheduled radical prostatectomy)

5. The interval between the diagnostic biopsy and the MRI/MRSI is ≥ 6 weeks.

6. Projected date of MRI/MRSI

7. Known contraindications for patient to undergo MRI/MRSI? (cardiac pacemakers, non-compatible intracranial vascular clips, metallic hip replacement, other metallic implants in the pelvic area or contraindications to endorectal coil insertion, allergic to latex, etc.)

8. Prior cryosurgery, surgery for prostate cancer including TURP, prostatic radiotherapy, androgen deprivation therapy or complementary alternative medicine?

9. Patient has agreed to undergo a Fleet’s enema in preparation for the MRSI exam.

10. Pathologic specimens from radical prostatectomy are available for central analysis

11. Release for medical information consent signed by participant

The following questions will be asked at Study Registration:

1. Name of institutional person registering this case

2. Has the Eligibility Checklist (above) been completed?

3. Is the patient eligible for this study?

4. Date the study-specific Consent Form was signed (must be prior to study entry)

5. Participant Initials (last, first)

6. Verifying Physician (Site PI)
### Patient’s ID Number (optional; code 99999)

### Date of Birth (mm-dd-yyyy)

### Ethnic category
1. Hispanic or Latino
2. Not Hispanic or Latino
3. Unknown

### Race
1. American Indian or Alaskan Native
2. Asian
3. Black or African American
4. Native Hawaiian or other Pacific Islander
5. White
6. More than one race
7. Unknown

### Gender

<table>
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<th>M</th>
<th>F</th>
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</table>

### Participant’s country of Residence
1. USA
2. Canada
3. Other

### Zip Code (U.S. Residents)

### Participant’s Insurance Status
0. Other
1. Private Insurance
2. Medicare
3. Medicare and Private Insurance
4. Medicaid
5. Medicaid and Medicare
6. Military or Veterans Administration
7. Self pay
8. No means of payment
9. Unknown/Decline to answer

### Will any component of the participant’s care be given at a military or VA facility?

<table>
<thead>
<tr>
<th>Y</th>
<th>N</th>
</tr>
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</table>

### Registration date (mm-dd-yyyy)

Completed by ___________________________  Date ___________________________

Name of person entering data onto the web ___________________________
Appendix IV
Page 39: A line has been added with “Name of Spectroscopist participating in this study at your site.”

The name “Robert Tew” has been replaced with “ACRIN Administrator, Attn. 6659 PSA”.

Appendix V
Page 40: The diagram in this appendix has been updated:

**APPENDIX V DIAGRAM OF THE PROSTATE**

![Diagram of the prostate]

Appendix VI
Pages 41-44: This appendix has been added:

**Appendix VI: QA SPECTROSCOPY SNR PROTOCOL**

Enter parameters for the QA protocol series I and II listed below and then save as “QA SPECTO”.

**SERIES I: Localizer Scan [landmark center of phantom]**

*Patient Protocols:* site
*Scan Mode:* Research
*Protocol name and number:* QA SPECTRO (number will be specific to site)

*Patient Information*
Patient ID: geservice
Patient Name: Probe-p SNR
Weight (LB): 111 (Important to enter this number)
Landmark: Nasion (Using the head coil cushion, center 5-inch surface coil on the pad and center the phantom atop the surface coil; then, landmark center strip of the phantom.) *See set up illustrations on page 44

Patient Position

Patient Position: Supine
Patient Entry: Head First
Coil Type: 5GP (5-inch surface coil)
Series Description: Localizer

Imaging Parameters

Scan Plane: 3 Plane
Monitor SAR: no entry /or if entry is required, Y (for yes)
Imaging Mode: 2D
Pulse Sequence: localizer
Imaging options: None
PSD Filename: None

Scan Timing

Number of Echoes: 1 (default)
ETL: no entry
Flip Angle: no entry
Te: 1.8 (default)
Rep Time(TR): 25.8 (default)
T1 Time: no entry

Scanning Range

Field of View: 26
Scan Thickness: 20
Spacing: 0
Center of FOV: R/L = 0, A/P = 0, S/I = 0
Number of scan locations: 3

Acquisition Timing

Acq. Matrix (freq): 256
Axq. Matrix (phase): 256
Frequency Direction: no entry
Phase FOV: 1.00
Prescan Options: Autoshim
Auto CF: Water
Nex: 1
**Imaging Time:** 20 seconds

---

**SERIES II: Spectroscopy scan**

**Patient Position**

Patient Position: **Supine**  
Patient Entry: **Head First**  
Coil: **5GP** (5-inch surface coil)  
Series description: **Probe-p SNR**

**Imaging Parameters**

Plane: **Axial**  
Mode: **MRS**  
Pulse Seq: **Probe-p**  
Imaging Options: **Ext. Dyn. Range**  
PSD Name: no entry

**Scan Timing**

*of Echoes: **1** (default)  
TE: **37**  
TR: **2000**  
FOV: **24**  
Voxel Thickness: **20**  
Spacing: **20**  
Locs per slab: **1**

**User CVs Screen**

CV3 scan mode: **1.00**  
CV4 total # of scans: **32.00**  
CV17 AWS optimization: **0**  
CV18 ROI Edge: **7**

---

**Scanning Range**

FOV: **24**  
Start: **S10**  
End: **R10**
Start: **L10**  
End: **P**  

*For A/P locations, move bottom of press box 1 cm anterior (up) from the bottom of the phantom.*

**Table Delta:** 0.00 (default)

Select: **Start**  
Select: **End**  
Select: **Accept**

**Acquisition Timing**

Freq: **1**  
Phase: **1**  
NEX: **2**  
Freq Dir: **R/L**  
Auto Center Freq: **Water**  
Select: **Autoshim**

Select: **Save Series**  
Select: **Prepare to Scan**  
Select: **Research Operations**

Select: **Display CVs**  
CV Value: **tempC** Enter: **24°**  
Select: **Accept**

Select: **Research Operations**  
Select: **Download**  
Select: **Auto Prescan** *(Very important to do Auto Prescan first)*  
Record: **Flip ang, SuppLvl, R1, R2, TG, and AX** values on the **QA Dataform**. These values will appear at the bottom of the screen when the Auto Prescan is finished.

Select: **Spectro Prescan**  
Record: the shim values on the **QA Dataform**.

Select: **Done**  
Select: **Scan**

**Imaging Time: approximately 1:44**

Record: **Spectral dataset values from Browser on QA Dataform.**
Illustrations of GE Brain phantom and 5-inch surface coil set up for Spectroscopy QA:

Appendix VII
Pages 45-46: This appendix has been added:
Appendix VII
Procedure To Set Up the Prostate Exams Under Functool 2

Thank you for your consideration.

Tess Thompson, M.Phil
Protocol Associate

cc:

Series selection under AW
  • Click on MR filter to get only MR images.
  • Select a patient by left clicking on the patient’s name.
  • Select the prose spectroscopy (postage stamp) data by left clicking on the sequence.
  • Select the appropriate localizer by pressing the ctrl key while left clicking the desired localizer image. At this point both the spectroscopy and image series should be highlighted in the browser.
  • Click on Functool 2 button to load it.
If Functool 2 is not a button on the tool bar:

- Open the Software Manager: In the left menu select More software/Software Manager.
- Select the software to move.
- Middle click drag and drop the software above the desired button to configure.

**Functool 2**

- Select 3D Prostate protocol.
- Window and level the background image by moving the mouse in the top left view, while pressing the middle mouse button.
- Hide functional map in lower left view. To do this, Middle click on the red 50% transparent active annotation and drag it to the right in order to hide the functional map (to reach 100% transparency).
- Remove undesired voxels from the lower left view. To do this, either:
  
  highlight the voxel to remove by selecting it with the mouse, then click on the scissor tool (or Ctrl + x). repeat for each voxel to eliminate.
  
  or

  click on the Create a Box ROI icon, found on the left side toolbar.

Adjust the box size and position with the mouse to define the voxels to eliminate (voxels will turn green when selected for removal). Additional voxels outside this rectangular box may be selected for removal by selecting them with the mouse. Once all voxels have been selected for removal, click on the scissors icon.

- To restore the ROIs in the top left view, click anywhere outside the box in that view.
- Press Space bar to autoscale the selected spectral ROIs in the upper views.
- Adjust the imagefov in the lower left by holding the middle mouse button over the red dfov annotation and dragging to the desired fov.
- To voxel shift, click the show/hide grid icon on the left side toolbar. This will cause a red grid to be displayed on the top left view. Drag the grid to the desired location and select 3D prostate followed by the compute button.
- Remove the PRESS Box by right clicking on the view to open the contextual menu and select Hide PRESS ROI.

- To save DICOM screen shots, move the mouse over the image and type shift + S. This will create a new series called SCREENSAVE, within the current exam.
- To push these screen shots to PACS, drag them with the middle mouse button to the PACS icon at the bottom of the Advantage Windows patient list window. This requires that a PACS destination icon has been defined with the Network Manager tool (click on the Tools, then Network Manager button found on the AW patient list browser left side toolbar).
**Display information:**

3. Click on the 3D Prostate button in order to call the protocol’s wizard.
4. Click on Advanced Settings then the Display tab.
5. Select or deselect the value to display or hide (select Creatine + Choline, Creatine + Choline / Citrate).
6. Save button preserves preferences for future sessions.
Schema:

“Within 3 months” has been changed to “Within six months” regarding the time frame that radical prostatectomy will be performed. This corresponds with the eligibility criteria.

Consent:

What are the Costs?

First paragraph has been deleted: “Taking part in this study may lead to added costs to you or your insurance company. If your insurance company does not pay for the MRI imaging, the American College of Radiology Imaging Network (ACRIN) will reimburse the costs of the MRI/MRSI exams. Please ask about specific details regarding reimbursement, any expected added costs, or insurance problems”.

Eligibility Checklist:

Questions #3 and #4: The word “projected” has been added.

Question #10 has been added: “Patient has agreed to undergo a Fleet's enema in preparation for the MRSI exam”.

Question #5 under Study Registration: “Initials (last, first)” has been added.

Question #8 under Study Registration: “(mm/yyyy)” has been added.

Question #10 under Study Registration: “Ethnicity” has been added.