



ACRIN Protocol 6660

SUMMARY OF CHANGES

November 22, 2006

Amendment # 5

In addition to the minor changes and edits that typically accompany protocol amendments which are listed below, we have revised the protocol to update contact information on the cover page, make revisions to the table of participating investigators, and perform various administrative edits.

COVER PAGE

The address for the statistician for the trial, Suddhasatta Acharyya, Ph.D., has been changed. It now reads:

Statistician
 Suddhasatta Acharyya, Ph.D.
 Center for Statistical Sciences
 121 South Main Street, 7th Floor
 Brown University, Box G-S121
 Providence, RI 02912
 (401) 863- 9873
 Fax: (401) 863-9182
acharyya@stat.brown.edu

The address for the co-principal investigator, Fredric A. Hoffer, MD, has been changed. It now reads:

Co-Principal Investigators
 Fredric A. Hoffer, MD
 Department of Radiology, R-5438
 Children's Hospital & Regional Medical Center
 4800 Sand Point Way NE
 Seattle, WA 98105
 (206) 987-2134
 Fax: (206) 987-2341
fred.hoffer@seattlechildrens.org

The phone number for **Co-Principal Investigator**, J. Brad Wyly, MD, has been changed from "404-325-6407" to "404-785-6532."

The zip code for the **Pediatric Oncologic Consultant**, Alison Friedmann, MD, MSc, has been changed from "02144" to "02114."

“Including Amendments #1-4” has been changed to “Including Amendments: 1-5.”

9.0 DATA COLLECTION FORMS (Page 22-23)

In section **9.1 Data Collection Forms** the “*IS form*” has been deleted. It stated:

IS - Proof of Truth for New Surgery, Diagnostic Procedure or Imaging, after 6 months and up to 36 months

In section **9.2 Data Collection Table** changes were made to indicate the section to refer to for the inclusion criteria for the trial. The referenced section has been changed from “5.5” to “5.1.” The changes appear under the following forms:

C2	CT Conventional Imaging Form	Submitted within 21 days of imaging. Local reader. *All imaging to be done within 14 calendar days of each other and within 2 months of diagnostic/operative procedures (see Section 5.1).
M4	MRI Conventional Abd/Pelvis Imaging Form	Submitted within 21 days of imaging. Local reader. *All imaging to be done within 14 calendar days of each other and within 2 months of diagnostic/operative procedures (see Section 5.1).
I6	Scintigraphy Imaging Form	Submitted within 21 days of imaging. Local reader. *All imaging to be done within 14 calendar days of each other and within 2 months of diagnostic/operative procedures (see Section 5.1).
M3	Whole-Body MRI Imaging Form	Submitted within 21 days of imaging. Local reader. *All imaging to be done within 14 calendar days of each other and within 2 months of diagnostic/operative procedures (see Section 5.1).
PT	PET Form	Submitted within 21 days of imaging (if optional PET is performed). Local reader. *All imaging to be done within 14 calendar days of each other and within 2 months of diagnostic/operative procedures (see Section 5.1).

In section **9.2 Data Collection Table** changes were made to Biopsy Form (BX). The phrase “check form for number of procedures and type. May have multiple forms” has been deleted and the phrase “*report one biopsy location per form*” has been added. It now states:

BX	Biopsy Form	Submitted within 21 days of biopsy procedure. *Biopsy procedures: report one biopsy location per form.
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In section **9.2 Data Collection Table** the “*IS form*” has been deleted. It stated:

IS Proof of Truth for New Surgery, Diagnostic Procedure or Imaging.

In section **9.2 Data Collection Table** the phrase “per form instructions” has been added to the F1 form. It now states:

F1 –	F1 – Long Term Follow-up Form @ 1, 2, 3 Years	Submitted within 21 days of follow-up at years 1, 2, and 3 from study enrollment <i>per form instructions.</i>
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11.0 IMAGING ASSESSMENT (Page 25)

The name and email address of the individual to contact for all imaging related questions has been changed from “Sharlene Snowden, ssnowdon@phila.acr.org” to “Anthony Levering, alevering@phila.acr.org.”

19.0 INSTITUTIONAL AUDITS (Page 44)

In section **19.4 Audit Source Documentation Table** changes were made to Biopsy Form (BX). The phrase “ check form for number of procedures and type. May have multiple forms” has been deleted and the phrase “*report one biopsy location per form*” has been added. It now states:

BX	Biopsy Form	Submitted within 21 days of Biopsy Procedure.	Completed and signed (Research Associate & Radiologist and/or Pathologist) and dated BX form. AND Reports: Diagnostic procedure report(s) and pathology report(s) Note: Biopsy procedures – <i>report one biopsy location per form.</i>
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APPENDIX III: PARTICIPATING INVESTIGATORS AND INSTITUTIONS (Page 60-61)

In the table listing participating investigators and institutions there have been changes made to include and delete investigators associated with the trial. The changes are as follows:

Allison Friedmann, MD has been added to the table. Her information is as follows:

<p><i>Allison Friedmann, MD Harvard Medical School Massachusetts General Hospital 32 Fruit Street, White 246 Boston, MA 02114 617-726-2737 afriedmann@partners.org</i></p>

Both Heike Daldrup-Link, MD and Katherine K. Malthay, MD have been removed from the table. Their information is as follows:

Heike Daldrup-Link, MD
Department of Radiology,
Box 0628
University of California,
San Francisco
San Francisco, CA 94143-
0962
Phone: 415-476-4328
Fax: 415-476-0616
daldrup@radiology.ucsf.edu

Katherine K. Malthay, MD
University of California,
San Francisco
Phone: 415-476-2275
malthay@radiology.ucsf.edu

Paul Babyn, MD has been added to the table. His information is as follows:

Paul Babyn, MD
The Hospital for Sick
Children
555 University Avenue
Toronto, Ontario M5G 1X8
416-813-5527
Fax: 416-813-5791
paul.babyn@sickkids.ca

The information for the co-principal investigator, Fredric A. Hoffer, MD, has been changed. It now reads:

Fredric Hoffer, MD, Co-
investigator
Pediatric Interventional
Radiologist
Department of Radiology, R-
5438
Children's Hospital & Regional
Medical Center
4800 Sand Point Way NE
Seattle, WA 98105
206-987-2134
Fax: 206-987-2341
fred.hoffer@seattlechildrens.org

Joseph Mammone, MD has been added to the table. His information is as follows:

Joseph Mammone, MD
Cancer Institute of New Jersey
1 Robert Wood Johnson Place
Dept. of Radiology, MEB #404
New Brunswick, NJ 08903
732-235-7721
germaine46@comcast.net

Mary McCarville, MD has been added to the table. Her information is as follows:

Mary McCarville, MD
St. Jude Children's Research
Hospital
Department of Radiology
Imaging
332 N. Lauderdale
Memphis, TN 38105
901-495-2399
Fax: 901-527-0054
Beth.McCarville@stjude.org

Stephan Voss, MD has been removed from the table. His information is as follows:

Stephan Voss, MD
Children's Hospital Medical
Center
Harvard
Cambridge, MA
617-355-8259
stephan.voss@tch.harvard.edu

At McMaster University "Margaret Pui, MD" has been removed from the table and "Carol Portwine, MD" has been added. The new contact information now states:

Carol Portwine, MD
McMaster University
1200 Main Street E.
Hamilton, ON L8N3Z5
(905) 521-2100, ext. 73428
portwc@mcmaster.ca

APPENDIX IV SPECIFIC CT, MRI, SCINTIGRAPHY, AND FDG-PET PROTOCOLS

(Page 62)

The name and email address of the individual to contact for all specific CT, MRI, Scintigraphy, and FDG-PET protocols has been changed from “Sharlene Snowdon, ssnowdon@phila.acr.org” to “Anthony Levering, alevering@phila.acr.org.”