



Making the Job Your Own: A Hands-On Workshop for Protocol Organization and Compliance

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Presentation Objectives

- Poor Planning Makes for Poor Performance
- Briefing a Protocol
- Tracking a Patient from On Study to Off Study

Proper Planning Prevents Poor Performance



Briefing a Protocol

- Training Requirements
- Other Involved Departments
 - Laboratory
 - Pathology
 - Radiology
 - Pharmacy

Example of Briefing

A071101

Study Briefing

SPECIAL NOTATIONS	REQUIREMENT DETAILS	REQUIREMENT COMPLETED Y/N
<u>LAB REQUIREMENTS</u> Yes	See Section 10.0	Mary Ann completed review
<u>QUESTIONNAIRES</u> None		
<u>TISSUE SUBMISSION</u> Yes	Training for lab/pathology	Staff who completed training: MAM, DR, WK, AVH, TM, Pathology slides in binder
<u>RT CREDENTIALING</u> None		
<u>RADIOLOGY REQUIREMENTS</u> Yes	See section 6.7	Reviewed and approved by radiology 2/13/2015
<u>TRAINING REQUIREMENTS</u> Yes	Study Chair approval and lab/path training	
<u>FUNDING/TEMPLATE</u> Yes	In CREDIT	Amy Reviewed
<u>MISC.</u> Yes	Vaccine order form	Per Marsha This could be filled out by the Study Nurse. The only thing we need to make sure of is that the shipping address is : Essentia Health Investigational Drug Room 1S2E20 420 East First Street Duluth, MN 55805 The other thing we need to make them aware of is that we only accept deliveries M-Thurs from 8 a.m. to 3 p.m.
<u>Outreach</u> None	Complete review for the following: <ul style="list-style-type: none"> • Lab • Radiology • Radiation • Treatment 	Ashland-NO Hibbing-NO Virginia-NO

Laboratory and Pathology

- Lab and Path Instructions
 - Created and updated by the Research Lab Coordinator
- Lab Orders with CPT Codes
 - Created and updated by the Research Lab Coordinator
 - Gives most cost effective labs to order for patient on protocol

Pathology Instructions

A071101 (Heat-Shock Vaccine in GBM) Study—Tumor Procurement, Preparation and Shipment

Study Coordinators: Deb Roding, RN (ext. 63105; pager 788-0177)
Wilma Knutson, RN (ext. 63111; pager 788-0188)
Amy Van Hecke, CRA (ext. 63088)

O.R. Contact: Marcie Hunker, RN (ext. 64977)

Lab Contacts: Mary Ann Miller, MT (pager 788-6580)
Sheila Tapper, Anatomic Path Supervisor (ext. 65472)
Lab Sendouts (ext. 18157)

Surgery will be scheduled through Oncology Clinical Trials, and information communicated to Mary Ann Miller, who will disseminate information to Pathology. If possible, surgery should be scheduled Monday-Wednesday (morning case) to optimize tissue viability. Tumor harvested on Friday must be stored frozen at -80°C ($\pm 20^{\circ}\text{C}$) for Monday shipment to Agenus. Agenus will not accept Saturday delivery. Oncology Clinical Trials will deliver Agenus kit to Histology the day before scheduled procedure. The kit contains all supplies required for tumor processing and shipment. OCT staff should fill out labels and patient information on the Tissue Procurement Form (TPF).

OR/Pathology/Histology: Follow instructions provided by Agenus. Key points for tumor processing:

- OR staff should wrap the tumor tissue in a sterile cloth and place in a basin on ice. Tissue should be transported STAT to Pathology (agreed-upon location per Dr. Carter).
- Use sterile technique and avoid cross-contamination with tissue or fluid from other patients.
- Pathologist should assess tumor viability—do not submit necrotic or cystic components of tumor to Agenus.
- Within 30 minutes, using sterile technique, section tumor tissue into 1-2 cm^2 sections. At least 7gms tumor should be sent. Place carefully, maintaining sterility, into the 50ml tubes provided in Agenus kit. Fill no more than $\frac{1}{2}$ - $\frac{2}{3}$ full.
- Label tubes with Agenus labels—make sure all required information is documented using a ballpoint pen.
- Freeze tissue immediately at -80°C (within 30 minutes of removal).
- Prep sections of tumor per routine local path. Also obtain a sample of at least 5mm^3 , fix in 4-10% neutral buffered formalin and prepare an FFPE block for biomarker analysis (per pp. 20-22 of protocol). The FFPE block will be shipped to the Alliance Biorepository at Mayo, NOT to Agenus.
- Notify Lab Sendouts (ext. 18157)—they will complete shipping process.

Sendouts: Communicate with Pathology and Oncology Clinical Trials to ship tumor ASAP per printed instructions from Agenus lab (Research file under A071101). Make sure all labels and forms are completed, that there are no discrepancies, and that sufficient dry ice is used (8kg).

Lab Instructions

A071101 (Heat-Shock Vaccine in GBM) Study—Lab Instructions

Study Coordinators: Deb Ronding, RN (ext. 63105; pager 788-0177)
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Lab Sendouts (ext. 18157)

Besides preparation of tumor specimen for transport to Agenus (for vaccine prep), each patient will also have local labs (blood and urine) and blood sendouts to Mayo for immune response analysis.

Timepoints for Mayo draws are dependent on treatment arm:

Arm 1 (vaccine + concomitant bevacizumab) = Draw before first vaccine dose, before vaccine dose #5, before vaccine dose #7, 2 weeks after final vaccine dose, and 2 weeks after final bevacizumab dose

Arm 2 (vaccine + bevacizumab at progression) = Draw before first vaccine dose, before vaccine dose #5, before vaccine dose #7, 2 weeks after final vaccine dose, and 2 weeks after final bevacizumab dose

Arm 3 (bevacizumab alone) = Draw before first bevacizumab dose, before bevacizumab dose #3, before bevacizumab dose #5, and 2 weeks after final bevacizumab dose

Patient will arrive with “kit” containing: 10 10ml NaHeparin tubes and labels.

Draw ~8.5mls blood into each of the 10 tubes, and invert gently to mix. Label tubes with:

Patient Information Label
Name of Study: A071101
Date & Time Drawn & Initials

Place the tubes on ice. Send samples and paperwork STAT to Sendouts area of Laboratory.

Processing: Refrigerate tubes immediately upon arrival to Sendouts. Obtain Alliance BioMS shipping manifest from Oncology Clinical Trials. Do not centrifuge or aliquot specimens; whole blood must be shipped on cold packs by overnight mail to Alliance BAP at Mayo:

BAP Freezer
ST-SL-16150 Third Street SW
Rochester, MN 55902

Essentia will NOT be processing PBMC's (per App. IV)—we are not a designated site.

Attention: See separate instructions for shipping tumor sections to Agenus on day of surgery. These are the samples that will be used to produce vaccine.

There will also be a tumor block sent to Mayo for biomarker analysis (Oncology Clinical Trials will arrange details with Histo/Path). (See p. 20-22 of protocol)

Lab Orders with CPT Codes

A071101 Lab Charges

Please note that all labs required by protocol have been listed, but no determination has been made regarding SOC or Research status.

Reviewed by: MAM 10/16/14 (per Update #4 dated 6/18/14)

PI: Bret Friday, MD

TEST	EPIC	CPT	Proc. Code	Pre-Registration	Registration	Day 1 of Each Cycle	Post-Treatment Follow-up
Serum HCG (WOCBP only)	Lab2624	84703	7752	X	X (≤ 16 days before treatment)		
Albumin	Lab9	82040	7914		X	X	
Alk. P'Tase	Lab4	84075	7908		X	X	
AST	Lab7	84450	7911		X	X	
ALT	Lab8	84460	7912		X	X	
Total Bilirubin	Lab5	82247	7909		X	X	
Glucose	Lab1	82947	7904		X	X	
Creatinine	Lab11	82565	7916		X	X	
CBC w/Diff	Lab2998	85025	99248		X	X	
Urine Protein-- suggest T. Protein/Creat Ratio	Lab4074	82570 + 84156	6951 + 84156		X	X (within 48hrs of bevacizumab cycles only)	
PT/INR	Lab2652	85610	7467		X	X (repeat for warfarin patients only)	
APTT	Lab2602	85730	7463				
RSEND	Lab1214	99001	7200	See p. 19 (Immune Monitoring): Arms 1 & 2 have 5 draws; Arm 3 has 4 draws			
Venipuncture	NA	36415	3641502	Invoice as needed when no SOC labs are drawn			

These orders will provide tests listed as "Clinical Lab Tests" (see p. 27, footnote 4)

Urine T. Protein/Creat Ratio is recommended test for random urine sample

Pathology is reviewing tissue procurement and shipment (for vaccine production)--to Sheila Tapper 10/16/14--order Lab 1214 with "Surgical Specimen from Pathology" in order comments

Radiology

- Communicate radiology portion of protocol via:
 - E-mail
 - Meetings
 - Radiology Summary Forms
- Send protocol with Radiology Summary form to Radiology manager
- Radiology manager forwards information to radiologists to approve at their scheduled meetings

Radiology Summary Form

ONCOLOGY CLINICAL STUDY SUMMARY

Name of study: A071101 – A Phase II Randomized Trial Comparing the Efficacy of Heat Shock Protein-Peptide Complex-96 (HSPPC-96) Vaccine Given with Bevacizumab versus Bevacizumab Alone in the Treatment of Surgically Resectable Recurrent Glioblastoma Multiforme (GBM)

Study Summary: To determine whether there is an overall survival advantage of HSPPC-96 administered with bevacizumab, given concomitantly or at the point of progression, in comparison with bevacizumab alone in patients with surgically resectable recurrent GBM

Modality involved: MRI (or CT only if MRI is contradicted) for Tumor Assessment

Modality protocol needed, technical parameters: MRI and CT obtained per local standard guidelines.

Radiologist dictation requirements: Per local standard guidelines

Technical charge: This will always be billed to patient and we will direct to study or patient insurance on the billing side by research coder.

Professional charge: This will always be billed to patient and we will direct to study or patient insurance on the billing side by research coder.

Do we get a copy of report if our radiologists are not reading? N/A Essentia Health Radiologist will complete the read.

Pharmacy

- Feasibility
 - Components
 - Sub-Components

Pharmacy Reminder Sheet

Study # A071101

Investigational agent is provided by study

HSPPC-96

All other drugs are commercially available.

PLEASE NOTE:
Please Contact Marsha & Emily,
Investigational Drug Room,
x63270 or 52077 to alert them of a
Potential Patient.

Tracking a Patient: On Study to Off Study

- General
 - Clinical Trial Management System (CTMS)
 - Outlook Calendar
 - Follow Up Tracking System
- Toxicities/Attribution
 - Chemo Sheets
 - MD Sign Off
- Oral Compliance
 - Pill Diaries (provided or not provided)
 - Study Nurse Dictation
- Dose Modifications
 - Study nurse double check system
 - MD Sign Off

Conclusion

Questions

