

As an employee of MPI Research, you have an obligation to report any and all Animal Welfare concerns. This form may be used to promptly inform the IACUC of an animal care issue.

TO BE FILLED OUT BY THE EMPLOYEE:

Date: 12/20/04-12/22/04, 12/24/04, and 1/15/05 Time: NA Location: NA

Study Number(s) (if known and applicable): 1096-004 Animal Number(s) (if known and applicable): 5001-5008

Concern: Eight Beagles were sent to Clinical Medicine for D83/VAP placement per the 1096-004 protocol, SOP CLM 52-4, and documented on approved MPI form CLM-21-2. Per protocol specifications VAP (vascular access port) placement was designated for the femoral artery. All eight animals were incorrectly implanted in the femoral vein.

The result was eight original implant surgeries, eight unnecessary repair surgeries to move the incorrectly placed VAP lines in the femoral veins to the femoral arteries, one emergency surgery for animal 5002 on Christmas Eve to repair a port placed too deeply to access with standard port flushing equipment, and one animal 5006 that was placed on veterinary consult on 1/15/05 due to limb function impaired in the right hind limb possibly caused by a failed VAP line.

Several steps in the setup process were missed by Clinical Medicine:

- 1096-004 protocol section 6, Animal Preparation states, "All animals transferred to study will be instrumented with a vascular access port (VAP) for blood sampling (for blood gas analysis). Surgical placement of the VAP and postoperative care will be conducted according to MPI Research Standard Operating Procedures".
- 1096-004 protocol section 7.10, Arterial Blood Gas Analysis states, "A blood sample (approximately 0.2 mL) will be collected from the femoral artery (via the VAP) from each animal on study".
- SOP CLM-52-4 states under Surgical Placement of Vascular Access Port, "A small incision is made over the femoral vein or artery".
- Approved MPI surgical form CLM-21-2 has two specific areas to document the option of implanting the femoral vein or artery and the option must be written into a blank space as indicated below:
 - A small incision is made over the femoral _____ approximately 2 cms of the vessel is cleared of surrounding adventia.
 - A small incision is made in the femoral _____ and a cannula is inserted and advanced toward the vena cava or abdominal aorta.
- Surgical staff performing implantations on 12/20/04 were being trained by a senior surgeon.
- For one of the surgical trainees initiation in VAP placement in canines by the training surgeon could not be located.
- A similar incident, in which protocol specifications were not adhered to, occurred in April 2004 on study 126-156 in which 19 pigs were mis-dosed requiring an additional 19 pigs to be scheduled for stent surgery. Although the surgical implant schedule supplied in a Departmental Notification to Clinical Medicine by the Study Director stated that each animal would receive 2 stents that were not identical (one stent labeled A and one labeled B), 126-156 protocol clearly states in section 4, Study Design, "Each animal will be implanted with a total of two identical Test article stents". The discrepancy was not noted prior to study initiation.

Reported by (Optional): _____ IACUC Member Reported to: _____ Date: _____