

**STATE OF RHODE ISLAND  
DEPARTMENT OF HEALTH**

**IN THE MATTER OF:  
THE MIRIAM HOSPITAL**

**CONSENT AGREEMENT**

The Department of Health (hereinafter "HEALTH") became aware of an occurrence of a wrong site arthroscopic surgical procedure on the wrong knee of a patient at The Miriam Hospital (hereinafter "TMH"). The Department of Health undertook a multi-disciplinary investigation in order to determine the root cause of the surgical error and to mandate appropriate corrective action.

**FINDINGS OF FACT**

1. Exhibits "A" attached contains a Statement of Deficiencies on CMS *Form 256 survey date September 25, 2008.*
2. Exhibit "B" attached contains a Statement of Deficiencies
3. Exhibit "C" a letter from CMS regarding Hospital status.

**AGREEMENT**

After consideration of the investigatory findings, HEALTH and TMH agree as follows:

1. The Miriam Hospital accepts a sanction of Reprimand.
2. TMH agrees to remediate technical problems that were identified during the HEALTH's inspection and TMH's root cause analysis of this wrong-sided surgery. The specific issues that TMH must remediate include the following:
  - a. revise and make consistent the hospital policy, the time out checklist and any peri-operative checklists (e.g., white board);
  - b. revise the "time out checklist" and the process that requires re-verification of the primary information for the following information:
    - patient name, gender, and date of birth
    - the type of surgery and surgical site
    - signed consent form
    - preoperative history and physical, imaging test(s) and result(s) if applicable

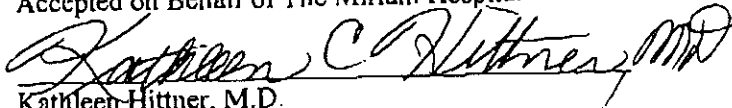
- verification that the surgical site marking is visible to at least two people (one of whom must be the attending surgeon).

This re-verification is done immediately prior to starting the surgery.

- c. use indelible ink to mark the correct surgical site unless such a marking is
    - i. impossible (e.g. intraocular surgery),
    - ii. the patient declines in writing to have their surgical site marked, or
    - iii. related to an emergency case
3. TMH agrees to contract within the next 45 days an external consultant/organization acceptable to the Department of Health to perform the following:
- a. Perform a comprehensive review of TMH's patient safety systems around surgical procedures that focuses on both the policy and protocols currently in place including:
    - the staff and organizational culture concerning patient safety
    - make recommendations regarding staff training
    - oversee implementation of revisions to the policy and protocols
    - monitoring of both policy effectiveness and the TMH staff compliance with the policy
    - review with the Department of Health all findings and recommendations.
  - b. Evaluate compliance with the hospital's Universal Protocol To Prevent Wrong Site, Wrong Procedure, and Wrong Person Surgery and time out process with direct observation at least twice a month for the next 12 months and report all findings and recommendations to TMH Board of Directors and to the Department of Health.
  - c. Design, implement and monitor a robust "near miss" reporting program for invasive procedures and update HEALTH on a monthly basis about the status of the program and total number of near misses reported each month for next 24 months.

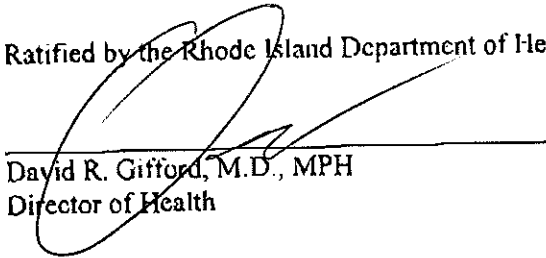
4. TMH agrees to have its Board of Directors actively involved in monitoring and reducing medical errors. This must include having a board member and CEO observe the time out process a minimum of once per month for the next 18 months. Additionally, a quarterly "impact statement" presentation to the hospital board by a patient/family member who has suffered a medical error at TMH for at least the next 24 months.
5. TMH agrees to contract with a state certified PSO no later than six months after the State certifies a PSO as outlined in Rhode Island General Laws § 23-17-21 that goes into effect January 1, 2009.
6. TMH agrees to participate fully in any statewide efforts to address medical errors including wrong site surgery efforts over the next 36 months.

Accepted on Behalf of The Miriam Hospital



Kathleen Hittner, M.D.  
President, CEO  
The Miriam Hospital

Ratified by the Rhode Island Department of Health on this 9<sup>th</sup> day of October 2008



David R. Gifford, M.D., MPH  
Director of Health