SUBJECT: ADVERSE TISSUE REACTION

Purpose of Procedure: To provide instruction for how to access and process Adverse Tissue Reactions

Policy Statement:

Rancho will investigate and track any suspected adverse reactions to bone/tissue implanted at Rancho.

Definition: An adverse reaction means a noxious (i.e., hurtful, injurious) and unintended response to a graft for which there is a reasonable possibility that the response may have been caused by the graft.

Key Point: Any adverse reaction which involves a communicable disease must be reported to the FDA within 15 calendar days of receipt of the information, if it is: 1) fatal, 2) life-threatening, 3) results in permanent impairment of a body function or permanent damage to body structure, or 4) necessitates medical or surgical intervention, including hospitalization.

Performed by: RN, MD

Policy:

1. Only musculoskeletal tissue purchased through an accredited nonprofit Tissue Bank will be used for implant. (See policy OR03 for handling and storage of musculoskeletal tissue)

2. All musculosketal tissue implanted or discarded will be entered into a hospital tracking log.
   The log will include the following information:
   - Patient name
   - Medical Record Number
   - Surgeon
   - Date
   - Type of implant
   - Catalog and Lot Number for identification and tracking of implant

3. Expired tissue will be disposed of through pathology department.

4. Infection control department will investigate all surgical wound infections and assess whether or not bone/tissue from a tissue bank was used during the surgical procedure.
   Key Point: All surgical wound infections will be reported to Infection Control Committee and Surgery Committee.

5. The Infection Control department will immediately notify the operating surgeon and operating room supervisor if surgical wound infection is suspected bone/tissue adverse reaction.

6. The department, in conjunction with Infection Control and the Operating Surgeon will investigate any adverse events related to bone/tissue infections.

7. The tissue bank will be notified immediately following investigation of suspected bone/tissue reaction.

8. No further bone/tissue with the same lot number of suspected adverse reaction bone/tissue will be used until completion of investigation.

Reviewed by: Jo-Ann Abesamis, BSN, RN,CNOR.

References:

Guidelines for Perioperative Practice 2018 Edition
Professional Staff Rules and Regulations
The Joint Commission Standards 2019-Tissue Adverse Reactions

02/16 – Reviewed
10/18 – Revised
10/21 – Reviewed