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Determination

Date: February 3, 2014

Protocol: Surgical Outcomes and Characteristics of Patients with mesh complications from pelvic organ prolapse and stress urinary incontinence surgery

IRB ID: 4619

Applicant: John Miklos, MD

TYPE OF REVIEW: Exemption from IRB Review Determination

Items Reviewed:

- Application for IRB Exemption
- Variable sheet

The above-listed applicant has requested Sterling IRB to make an exemption from IRB review determination for the above-listed study.

Following review, the Sterling IRB Chairman (or designee) has determined that:

The above-listed study is exempt from IRB review pursuant to the terms of the U.S. Department of Health and Human Service's Policy for Protection of Human Research Subjects at 45 C.F.R. §46.101(b).

Sterling IRB's exemption determination is based on the study-related information available to Sterling IRB as of the determination date listed above. Should any changes be made to the study subsequent to Sterling IRB's determination, this determination is no longer applicable.

Authorized Signature