Principal Investigator: Dr. K. Maslow
Sponsor: Internal funds

Protocol Reference Number: B2007:044
Date of REB Meeting: March 26, 2007
Date of Approval: September 4, 2007
Date of Expiry: March 26, 2008

Protocol Title: "Randomized Clinical Trial Comparing TVT SECUR System (TVT S) and Trans Vaginal Obturator Tape (TVT-O) for Surgical Management of Stress Urinary Incontinence"

The following is/are approved for use:

- Protocol dated August 5, 2007
- Research Participant Information and Consent Form, Version dated August 28, 2007
- TVT5 study form, TVTS Intra and Post-Operative form, TVTS 8 week form and TVTS 1 year form submitted August 29, 2007
- Urogenital Distress Inventory Questionnaire and Incontinence Impact Questionnaire Version: Volume 3 1994 Quality of Life Research

The above was approved by Dr. Nicholas Anthonisen, Chair, Biomedical Research Board, Bannatyne Campus, University of Manitoba on behalf of the committee per your letter dated August 29, 2007. The Research Ethics Board is organized and operates according to Health Canada/ICH Good Clinical Practices, Tri-Council Policy Statement, and the applicable laws and regulations of Manitoba. The membership of this Research Ethics Board complies with the membership requirements for Research Ethics Boards defined in Division 5 of the Food and Drug Regulations.

This approval is valid for one year from the date of the meeting at which it was reviewed. A study status report must be submitted annually and must accompany your request for re-approval. Any significant changes of the protocol and informed consent form should be reported to the Chair for consideration in advance of implementation of such changes. The REB must be notified regarding discontinuation or study closure.

This approval is for the ethics of human use only. For the logistics of performing the study, approval should be sought from the relevant institution, if required.

Sincerely yours,

[Signature]

Nicholas Anthonisen, MD, Ph.D
Chair,
Biomedical Research Ethics Board
Bannatyne Campus

Please quote the above protocol reference number on all correspondence.
Inquiries should be directed to the REB Secretary
Telephone: (204) 789-3255/ Fax: (204) 789-3414
APPROVAL FORM

Principal Investigator: Dr. K. Maslow
Sponsor: Internal funds

Protocol Reference Number: B2007:044
Date of Approval: November 6, 2007

Protocol Title: "Randomized Clinical Trial Comparing TVT SECUR System (TVT S) and Trans Vaginal Obturator Tape (TVT-O) for Surgical Management of Stress Urinary Incontinence"

The following is/are approved for use:

- Research Participant Information and Consent Form, Version dated October 30, 2007

The above was approved by Dr. Nicholas Anthonisen, Chair, Biomedical Research Board, Bannatyne Campus, University of Manitoba on behalf of the committee as per your letter dated October 30, 2007. The Research Ethics Board is organized and operates according to Health Canada/ICH Good Clinical Practices, Tri-Council Policy Statement, and the applicable laws and regulations of Manitoba. The membership of this Research Ethics Board complies with the membership requirements for Research Ethics Boards defined in Division 5 of the Food and Drug Regulations.

A study status report must be submitted annually and must accompany your request for re-approval. Any significant changes of the protocol and informed consent form should be reported to the Chair for consideration in advance of implementation of such changes. The REB must be notified regarding discontinuation or study closure.

This approval is for the ethics of human use only. For the logistics of performing the study, approval should be sought from the relevant institution, if required.

Sincerely yours,

[Signature]

Nicholas Anthonisen, MD, Ph.D
Chair,
Biomedical Research Ethics Board
Bannatyne Campus

Please quote the above protocol reference number on all correspondence.
Inquiries should be directed to the REB Secretary
Telephone: (204) 789-3255/ Fax: (204) 789-3414

www.umanitoba.ca/faculties/medicine/research/ethics
Research Review Committee
Approval Form

Principal Investigator: Dr. Ken Maslow

RRC Reference Number: RRC/2007/0811

Date: December 14, 2007

Protocol Title: Randomized Clinical Trial Comparing TVT SECUR System (TVT S) and Trans Vaginal Obturator Tape (TVT O) for Surgical Management of Stress Urinary Incontinence

The following is/are approved for use:

- Protocol dated August 5, 2007
- Research Participant Information and Consent Form dated October 30, 2007
- Urogenital Distress Inventory questionnaire submitted March 20, 2007
- Incontinence Impact Questionnaire submitted March 20, 2007
- TVTS study form TVTS Intra and Post Operative form, TVTS 8-week form and TVTS 1 year form submitted March 20, 2007

The above was approved by Dr. B. Light, Chairperson, Research Review Committee, St. Boniface General Hospital, on behalf of the Committee. As the recommendations by the Research Review Committee have been met, final approval is now granted.

Any significant changes to the study Protocol and Informed Consent Form, must be reported to the Research Review Committee along with any other documents required as per Standard Operating Procedures for Clinical Investigators.

Sincerely yours,

[Signature]

Dr. B. Light
Chairperson, Research Review Committee
St. Boniface General Hospital
Please quote the above reference number on all correspondence.
Inquiries should be directed to the RRC Secretary
Telephone: (204) 235-3623   Fax: (204) 237-9860
N1004 – 409 Taché, Winnipeg, MB, Canada  R2H 2A6

cc:  
Dr. C. Gupta and Ms. Lise Girouard, Co-Investigators
Dr. M. Helewa, Clinical Director, Woman and Child Program
Dr. M. Morris, Clinical Director, Women’s Health
Ms. Noelie Lavergne, Program Director, Woman and Child Program
Dr. R. Guzman, President of the Medical Staff
Ms. Kris Ryan, Laboratories
Ms. V. Ryplanski, Financial Services
Ms. Debi Wilson, Patient Registration