AXIS Protocol

Cover Page

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Axis Allograft Dermis for female Pelvic Floor Repair: a Prospective Post Market Study

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Axis™ Allograft Dermis for Female Pelvic Floor Repair: a Prospective Post Market Study

Clinical Investigational Plan (CIP)

[redacted]

Investigational Plan #: CP009SU

Signature page

[redacted]

SPONSOR	INVESTIGATOR
Coloplast Corp. 1601 West River Road North Minneapolis, MN 55411 USA 800-788-0293	Name Address Postal code and city Country Telephone number:
APPROVER	
[redacted]	
[redacted]	Name and title of the Investigator
Date [redacted]	Date
[redacted]	
[redacted]	
Date	
[redacted]	
Date	

Table of Contents

1 Protocol Summary

Title	Axis™ Allograft Dermis for female pelvic organ prolapse repair: a post market study
Sponsor	Coloplast Corp. 1601 W. River Road Minneapolis, MN 55411
Product	Axis Allograft Dermis
Study Design	A prospective, single arm, multi-center, post market study of the efficacy of Axis™ Allograft Dermis for anterior, posterior or combined female pelvic floor repair.
Primary Objective	POP-Q Stage improvement from baseline at 1 year post operatively, categorized as cure, improved or failed.
Secondary Objective	POP-Q Stage at 6 weeks, 6 months, 2 year, and 3 year follow-up [redacted]
Brief Entrance Criteria	Diagnosed with clinically significant pelvic organ prolapse of Stage 2 or higher as determined by POP-Q prolapse grading requiring surgical intervention in the anterior, posterior or combined (anterior and posterior) compartment. Must be willing and able to complete all follow-up visits and procedures indicated in this protocol No prior prolapse implant or procedure No concurrent surgical treatment of prolapse using anything other than Axis No history of previous pelvic radiation No severe urogenital atrophy No immunosuppression and/or current systemic steroid use No contraindication to the surgical procedure
Visit Schedule	Study visits will take place at baseline, implant/hospitalization, 6 weeks, 6 months, 1 year, 2 years, and 3 years post operatively.
Scope	This study will target enrollment of 70 to 100 subjects at 5 to 10 US investigative sites.

2 Background

A woman's organs can shift position overtime as she ages or, in some cases, it can happen without any notice or warning. Pregnancy, childbirth, genetic predisposition, menopause, prior pelvic surgery, connective tissue disorders, and factors associated with elevated intra-abdominal pressure such as obesity, chronic constipation, and excessive straining can stretch and weaken the muscles that support the pelvic organs. A sheet of muscles, ligaments, and connective tissue called the pelvic floor supports

the uterus, small intestine, colon and bladder. If pelvic floor muscles are weak, the organs may drop, protruding into the vagina causing a Pelvic Organ Prolapsed (POP).

This condition affects millions of women and with the advancing age of the U.S. population, health care providers are likely to encounter women with pelvic organ prolapse with greater frequency. A woman's lifetime risk (up to the age of 80 years) for undergoing prolapse surgery has been estimated at 11 percent[1]. Approximately 200,000 inpatient procedures for prolapse are performed annually in the United States alone[2].

Pelvic organ prolapse can be categorized into four areas:

Cystocele or anterior prolapse: When the vaginal wall weakens and allows the bladder to protrude into the vagina from above.

Vaginal vault or uterine prolapse: When the top of the vagina loses its support and drops.

Rectocele or posterior prolapse: When the back of the vagina weakens and allows the rectum to protrude into the vagina.

Enterocele: When the small intestine drops and protrudes into the vagina. This usually occurs in conjunction with one or more of the other types of prolapse listed above.

Depending on the severity and stage of prolapse, many women do not need treatment. Some women find that their symptoms are relieved through special pelvic muscle exercises call Kegel Exercises, which are used to strengthen the muscles that surround the opening of the urethra, vagina, and rectum. Making dietary changes, maintaining a healthy weight, not smoking, and avoiding heavy lifting and straining also help to relieve symptoms. Medication is available to help treat urinary and bowel symptoms of POP. Further, a device called a pessary can be inserted into the vagina to support the pelvic organs. For women who can be fitted properly and whose pelvic organ support can be maintained with a pessary, this form of treatment has a high probability of success.

[redacted]

3 Product Description

Coloplast's Axis™ Allograft Dermis consists of [redacted], preserved human collagen. [redacted]

4 Study Purpose and Design

This study is a prospective, single arm, multi-center, post-market study to evaluate the efficacy of Axis™ Allograft Dermis used for anterior, posterior or combined (anterior and posterior) pelvic organ prolapse repair. Target enrollment is 70-100 subjects enrolled at 5 to 10 investigational sites in the United States. [redacted]

5 Objectives

5.1 Primary Objective

The primary objective of this study is to evaluate efficacy of the Axis Dermis graft used for soft tissue repair, replacement, reconstruction, or augmentations in the correction of POP as assessed by POP-Q Stage improvement based upon an objective grading of prolapse of the anterior, posterior or combined anterior and posterior (assessed individually) compartment(s) compared between baseline and one year. Grading of the prolapse will be categorized as follows:

Cured: POP-Q Stage reduced to 0 or 1, or improved by 2 stages from baseline

Improved: POP-Q Stage > 1, but improved by 1 stage from baseline

Failed: POP-Q Stage stayed the same or increased in severity from baseline

5.2 Secondary Objectives

Secondary objectives will assess POP-Q Stage and patient satisfaction at 6 weeks, 6 months, 2 years, and 3 years post implant, as follows:

Change in prolapse stage from baseline as determined objectively by POP-Q prolapse grading at 6 weeks, 6 months, 2 year, and 3 year follow-ups. Change in patient satisfaction from baseline and quality of life measured through validated questionnaires (PDFI-20 and PFIQ-7)[6]

Change in patient sexual satisfaction from baseline measured through a validated questionnaire (PISQ-12)[7]

Summary of Patient Global Impression of Improvement (PGI-I) for urogenital prolapse[9] results

Summary of The Institute for Female Pelvic Medicine & Reconstructive Surgery Surgical Satisfaction Questionnaire (SSQ-8) results[10]

Change in Pelvic and Sexual Health Institute Visual Analog Scale (VAS)[11] results

Surgical revision rate of the index prolapse(s)

Summary of all mild, moderate, and serious product and/or procedure related adverse events

6 Study Population

6.1 Participant Population

The study population will be adult female patients with pelvic organ prolapse, POP-Q Stage ≥ 2 that are clinically indicated for surgical intervention with Axis human tissue in the anterior, posterior or combined (anterior and posterior) compartments at the institutions designated for this study. All study candidates must be able to understand the nature of the procedure, provide written informed consent, and be available for follow-up at an approved investigational site.

6.2 Number of Participants

This study will target enrollment at 70-100 subjects at 5 to 10 investigational sites in the US.

6.3 Inclusion Criteria

Patients must meet all of the following criteria to be included in the study:

1. Adult female at least 18 years of age.
2. Willing and able to provide written informed consent.
3. Confirmed pelvic organ prolapse (POP) of Stage 2 or higher as determined by POP-Q prolapse grading requiring surgical intervention in the anterior, posterior or combined (anterior and posterior) compartment.
4. Willing and able to complete all follow-up visits and procedures indicated in this protocol.

6.4 Exclusion Criteria

Patients who meet any of the following criteria are excluded from entry into the study:

1. Concurrent surgical treatment of pelvic organ prolapse using anything other than the Axis Dermis. [Note: concurrent mid-urethral sling placement for treatment of stress urinary incontinence is allowed].
2. Confirmed Stage 2 or higher prolapse as determined by POP-Q prolapse grading for a compartment that is **not** being repaired in the same procedure. (Concurrent POP-Q Stage 1 repair is at the physician's discretion.)
3. Previous pelvic organ prolapse repair using biologic, or synthetic grafts. [Note: previous mid-urethral sling for treatment of stress urinary incontinence is allowed]
4. Pregnant or a desire to become pregnant in the future.
5. Previous radiation or other treatments for cancer in the pelvic area.
6. Severe urogenital atrophy.
7. Immunosuppression and/or current systemic steroid user.
8. Any contraindication to the surgical procedure.

7 Enrollment

After it has been determined that a potential study participant meets the entrance criteria and prior to data being collected, an informed consent must be obtained. There is no formal screening process outside of standard of care procedures required to determine participant eligibility. [redacted] Once it is determined the participant meets all of the inclusion and none of the exclusion criteria, they are considered enrolled in the study. When they are enrolled they will receive a subject number.

8 Procedures

Clinical data will be collected at baseline, implant, 6 weeks, 6 months, 1 year, 2 years, and 3 years post-operatively. The Data Collection Schedule below provides an outline of what clinical and participant data is collected at each visit (Table 1).

8.1 Data Collection Schedule

8.2 Baseline

The following will be collected at baseline:

Consent Form Obtained

The signed and dated consent form will be obtained prior to any study information being collected at the Baseline Visit.

Entrance Criteria Verified

The inclusion/exclusion criteria will be verified at the Baseline Visit.

Demographics, Medical History

Participant demographics, medical history related to pelvic organ prolapse, and other relevant medical history will be collected.

Subject evaluation/examination required within 6 months of the implant procedure

Objective POP-Q prolapse grading [redacted]

Clinical exam

Other Symptoms

Urinary symptoms

Colo-rectal symptoms

Incontinence measures, if applicable and standard of care (Uroflowmetry, Cystoscopy)

Participant Questionnaires required within 6 months of the implant procedure.

Pelvic Floor Distress Inventory Short Form (PFDI-20)

Pelvic Organ Prolapse/ Urinary Incontinence Sexual Function Questionnaire (PISQ-12) [for sexually active subjects]

Pelvic Floor Impact Questionnaire Short Form (PFIQ-7)

Pelvic and Sexual Health Institute Visual Analog Scale (VAS)

8.3 Implant Procedure

The surgical technique for POP repair using tissue is widely variable and dependant on physician training female anatomy, and preference. [redacted]

The implant of Axis will be documented on the Procedure Form. In addition, study product or procedure related adverse events will be recorded.

The Initial Implant Procedure Form should be entered into the database within 72 hours after the implant is completed.

8.4 Follow-Up Schedule

Follow-up visits are required at 6 weeks, 6 months, 1 year, 2 years, and 3 years post implant. If the participant misses any required follow-ups, a Study Deviation Form must be completed. Every attempt should be made to complete the visit, however, if the subject cannot be seen in person the required questionnaires should be mailed to the participant with a postage paid return envelope. If a scheduled visit is not within the follow-up window, the visit should still be completed as soon as possible and a Study Deviation Form completed.

Table 2 Follow-up Schedule & Visit Windows

Follow-Up	Window Start	Target Day	Window End
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

8.5 Follow-Up Visits

8.6 Revision Procedure

If during the follow up period a subject requires urogynecological surgery (i.e. additional or revision POP repair, mid-urethral sling, hysterectomy, etc.), complete the Revision Form. If a revision procedure is performed as the result of an adverse event (e.g. infection, rejection, pain), complete the Adverse Event form in addition to the Revision form.

9 Study Product

All investigative sites will be required to maintain an adequate stock of Axis Dermis. The lot number and size of each product used will be recorded on the Procedure Form.

10 Protocol Deviations

A protocol deviation is defined as an event where the clinical investigator or site personnel did not conduct the study according to the clinical investigational plan or the investigator agreement. All protocol deviations must be documented on a Study Deviation Case Report Form.

Reporting of protocol deviations should comply with local IRB policies and/or local laws.

11 Adverse Events

11.1 Adverse Event Definitions

An Adverse Event (AE) is any undesirable clinical occurrence in a participant regardless of whether or not it is related to the product or procedure. Any pre-existing condition that exhibits a change in nature, severity, or degree of incidence is also considered an AE.

A Serious Adverse Event (SAE) is an Adverse Event that results in one or more of the following outcomes:

Life Threatening: The participant was at eminent risk of dying at the time of the adverse event.
Permanent Impairment: An adverse event that resulted in permanent impairment of a body function or permanent damage to a body structure.
Necessitates Intervention: An adverse event that resulted in a condition that necessitates medical or surgical intervention to preclude permanent impairment of a body function or damage to a body structure.
Hospitalization/Prolongs Hospitalization: Requires inpatient hospitalization or prolongs an existing hospitalization.
Results in Death: An adverse event that results in the participant's death.

An Adverse Reaction (AR) is a noxious and unintended response to any Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) for which there is a reasonable possibility that the HCT/P caused the response.

[redacted]

11.2 Adverse Event Classification

The investigator will be asked to assess the relationship of the event to the implanted product, the implant procedure, and the presence or performance of the tissue itself for each adverse event reported.

A product related adverse event is an Axis Dermis related adverse event that results from the presence or performance of the product. [redacted]

A procedure related adverse event is an adverse event that occurs due to the implant procedure**.** Procedure related events can include, but are not limited to:

Adhesion
Anaesthesia reaction
De Novo dyspareunia
Fistula formation
Hematoma
Infection
Inflammation
Major nerve supply injury
Major vascular injury
Nerve injury or damage
Pain (lasting >6 weeks post-operatively)
Perforation (e.g. bladder, urethra, ureter, and bowel)
Urinary Retention directly related to the procedure and requiring surgical intervention and/ or prolonged catheterization lasting greater than 28 days
Voiding dysfunction not including urinary retention (e.g. Dysuria or obstruction)
Wound dehiscence

11.3 Adverse Event Reporting Requirements

Any mild, moderate, or severe adverse events possibly or probably related to the product and/or procedure, including Adverse Reactions, must be reported for purposes of this study protocol.

Any Serious Adverse Events, including Adverse Reactions, possibly related to the product and/or procedure must be reported to the Sponsor within 10 working days.

11.4 Adverse Event Review

An Independent Medical Advisor will review all Serious Adverse Events and Adverse Reactions on a periodic basis to be determined by nature and number of reported serious adverse events.

12 Withdrawal / Study Exit

In the event that a participant is unable or unwilling to continue participation in the study, notify Coloplast as soon as possible.

If a participant expresses the desire to withdraw from the study, a Withdrawal / Study Exit Case Report Form must be completed. The reason for participant withdrawal must be documented on this form.

In the case that the participant fails to comply with the follow-up schedule, the study site must make multiple attempts to contact the participant (e.g. telephone, registered mail). Each attempt to contact the participant must be documented in the participant's records. In the case that the participant is determined to be lost to follow-up, a Withdrawal / Study Exit Case Report Form must also be completed.

Participants will be considered to have completed the study after their two year follow up visit has been completed and all outstanding adverse events have been resolved or are permanently ongoing.

13 Electronic Case Report Forms (eCRFs)

The eCRFs are designed to accommodate the specific features of the study design and will be used to capture study specific data and store in a secured FDA 21 CFR 11 compliant database. Training will be provided for all study personnel entering data into the electronic database prior to being given access to the database.

Sites will enter data on eCRFs using Electronic Data Capture (EDC). All visit information will be captured in the EDC system. [redacted] The data from the questionnaires will be entered by the site into the EDC system after completion.

The investigator or relevant staff member who has signed the eCRF Authorization Log may complete the eCRF. The investigator will review all eCRFs for completeness and electronically sign the forms.

14 Statistical Methods

The key endpoints are specified below:

Efficacy**:** Efficacy metrics will include objective POP-Q prolapse grading as well as patient satisfaction (as measured by subject questionnaires) post-operatively at [redacted]

Safety**:** Safety will be measured through procedural and product related adverse events. Procedural complications will be collected during hospitalization. Serious product and procedure related events will be collected through 3 years post implant via the Adverse Event Form.

14.1 Sample Size

In the absence of predefined hypotheses, the desired sample size is based on the precision of estimates and half-widths of confidence intervals. The target enrollment cohort of 70 to 100 will provide between 60 and 85 evaluable subjects at month 12 [redacted]

Table 3 Sample Size Calculations

[redacted]

14.2 Statistical Analysis

[redacted] Results will be compared to competitive products from the available literature.

The primary analyses will include all subjects enrolled and followed. Additional analyses will be conducted where results are tabulated separately for subjects who require a revision procedure in one or both compartments and receive a product other than Axis Dermis and those who do not receive any additional product other than Axis Dermis during study follow-up.

15 Data Quality Assurance

15.1 Data Management

Coloplast will be responsible for data management and statistical analysis. Edit checks will be created for quality control of all data collected. Data will be subjected to initial inspection for omitted data, data inconsistencies, and deviations. The resolution of any inconsistencies will be resolved through Data Query Forms (DQFs). The site will be asked to review and respond to the DQFs generated by Coloplast.

15.2 Monitoring

It is the responsibility of Coloplast to ensure that proper monitoring of this investigation is conducted. Appropriately trained personnel appointed by the study sponsor will perform all monitoring that is done and will ensure that the investigation is conducted in accordance with the Monitoring Plan, the signed Investigator Agreement, and applicable laws.

During the period of the investigation, monitoring will be performed at the study site to assure compliance with study protocol. The monitor must be allowed access to the participant's files. The monitor will review the participant's records and consent forms and regulatory and study management documents to assess the accuracy of the data and study progress. Any concerns that result from this review will be documented and discussed with site personnel. The site investigator or delegated research staff will work with the monitor to resolve all queries. Resolution of these items and completion of assigned tasks will be documented by the monitor.

Monitoring visits will occur based on enrollment rates, duration of the study, site compliance, and data quality at each investigative site. Monitoring visits will be performed at least once at all enrolling sites. For sites that do not enroll participants, a telephone closeout visit will be completed.

15.3 [redacted]

[redacted]

16 Regulations and Guidances

[redacted]

[redacted]

Further, this study will be registered on www.ClinicalTrials.gov.

16.1 Consent

All participants will be required to sign an Informed Consent Form for participation in this study. In order to obtain informed consent, each participant must be informed about the investigation, acknowledge that participation is voluntary, and sign and date a consent agreement prior to collection of any study-related data. The Informed Consent should be provided to the participant in a language that he/she can read and understand. After the information contained in the Informed Consent document has been reviewed with each participant, the participant must sign and date the document, indicating willingness to participate in

the clinical study. In the event the participant cannot read, witnessed informed consent will be allowed. The participant should be given a copy of the Consent Form.

16.1.1 Requirements

A sample informed consent document suitable for use in this study, including the elements of informed consent in conformance with 21 CFR Part 50 will be provided by the sponsor. Iterations of this document must also include the elements of informed consent in conformance with 21 CFR Part 50 and should be approved by the sponsor prior to IRB review. Participants must be presented with the most current, IRB approved version of the consent form for signature and enrollment.

16.2 Institutional Review Board

This protocol and/or other relevant documents should be submitted to the appropriate local Institutional Review Board (IRB). Written approval must be obtained before commencement of the investigation. Approval obtained from the local IRB should document the version of the protocol and consent for that is being approved.

Any amendment to the protocol that impacts the conduct of the study will also be submitted to the same IRB.

16.3 Data Protection

All information collected during the course of this investigation will be kept strictly confidential. Any information that could identify a participant will remain with the investigator where it will be archived with study documents. Participants will remain anonymous for the purposes of data analysis. Data collected for the purposes of this study should be made available for Coloplast at all monitoring visits.

Should the investigation require future review, it may be necessary to allow limited access to Coloplast and regulatory authorities for audit purposes only.

17 Publication

Coloplast will form a publication committee that includes at a minimum the Study Principal Investigator and at least one other participating investigator. The committee will develop a publication strategy in collaboration with Coloplast. The scientific validity and timing of publications will be evaluated in order to maximize the benefits derived from the publication of the clinical data of the study.

18 Records and Retention

18.1 Sponsor Responsibilities

Coloplast, the study sponsor will maintain the following records:

All correspondence which pertains to the investigation

Signed Investigator Agreements, financial disclosure information, and current curriculum vitae

IRB approval correspondence

Adverse events, deaths, and complaints

All case report forms submitted by investigator, samples of informed consents/ applicable privacy protection authorizations, investigational plan and report of prior investigations

Study training records for all site personnel

Monitoring reports

Study reports

18.1.1 Sponsor Reports

The following table details submission requirements for each report.

Table 4 Sponsor Reports

Report	Submit To	Description
Adverse Reaction	Investigators' IRBs and FDA, as applicable	Notification within 15 working days after the sponsor first learns of the effect.
Withdrawal of Local IRB approval	Investigators' IRBs	Notification within 5 working days.
Recall and product disposition	Investigators' IRBs, as applicable FDA/ Applicable Competent Authorities	Notification within 30 working days; will include the reasons for any request that an investigator return, repair, or otherwise dispose of any products.
Progress Reports	Investigators' IRB, as applicable	Annually
Final report	Investigators' IRB, as applicable	Coloplast will notify the investigators of the completion or termination of the investigation. Investigators will, in turn, inform their IRBs. A final report will be submitted to the investigators and IRBs within six months after completion or termination of this study.

18.12 Records Retention

The sponsor will archive and retain all remaining documents pertaining to the investigation for a minimum of 10 years.

18.2 Investigator Responsibilities

In addition to the requirements stated in the investigator agreement, the investigator is responsible for the preparation (review and signature) and retention of the records cited below. All of the records below, with the exception of case history records, should be kept in the Investigator Site File (i.e., the study binder provided to the investigator). The following records are subject to inspection and must be retained according to the agreed upon timeframe in the investigator agreement (or longer as local law or hospital administration requires) after study closure.

All substantial correspondence that pertains to the conduct of the investigation. Any correspondence describing rationale for decisions made affecting participant safety and privacy or data collection and reporting is considered substantial correspondence.

Participant's case history records including: signed informed consent/applicable privacy protection authorization form; observations of adverse events/adverse device effects; medical history; implant and follow-up data; documentation of the dates and rationale for any deviation from the protocol.

[redacted]

[redacted]

[redacted]

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
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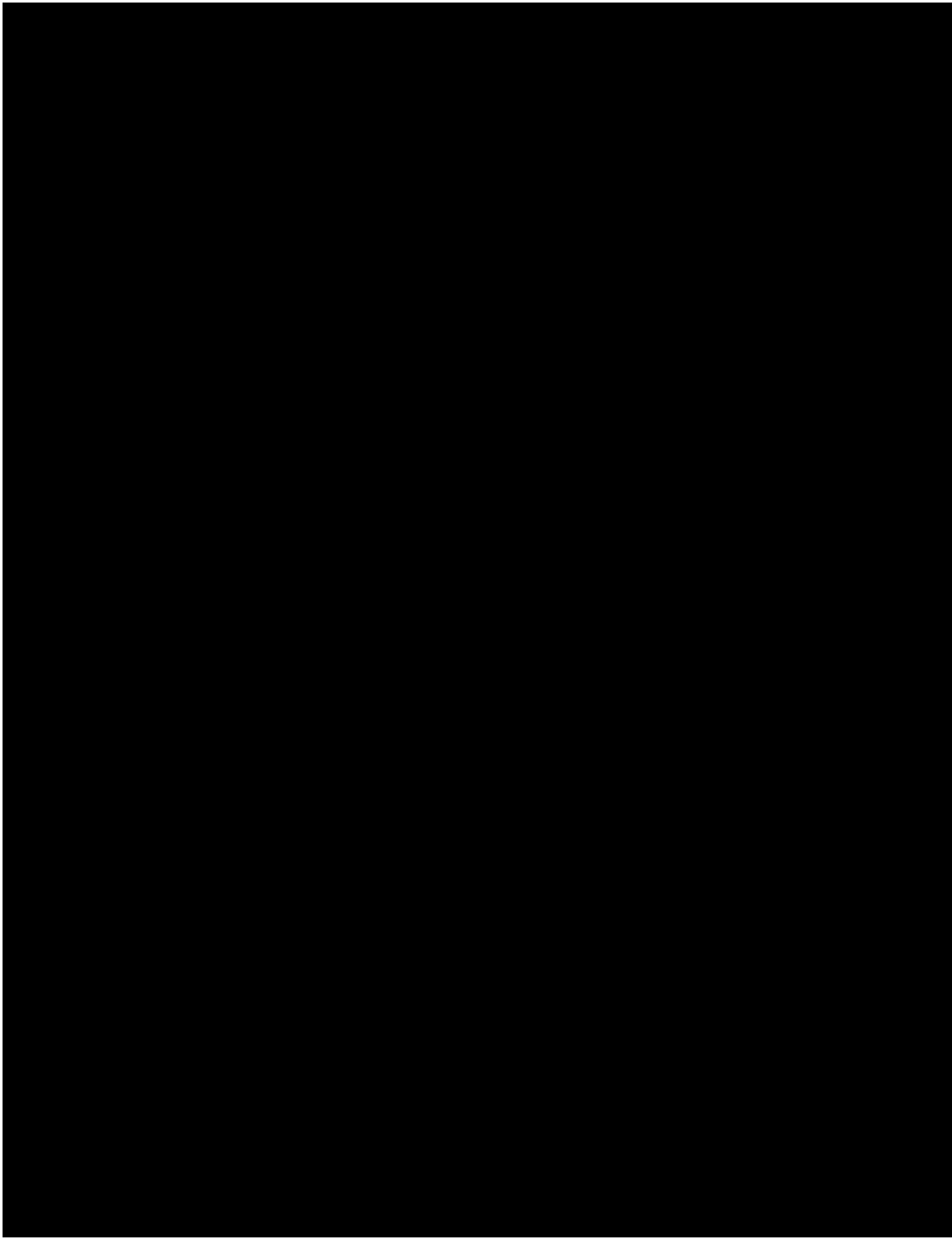

Appendix B: Patient Questionnaires

Patient Global Impression of Improvement for Urogenital Prolapse (PGI-I for Urogenital Prolapse)

Subject ID:__ __ __ -__ __ __

Visit Date: __ __/__ __/__ __ __ __
MM/DD/YYYY

1. **Check the box that best describes how your urinary tract condition is now, compared with how it was before you had the operation.**

☐ [1]Very much better ☐ [2]Much better ☐ [3]A little better ☐ [4]No change

☐ [5]A little worse ☐ [6]Much worse ☐ [7]Very much worse

Reference:

Srikrishna S, Robinson D, Cardozo L. Validation of Patient Global Impression of Improvement (PGI-I) for urogenital prolapse. Int Urogynecol J (2010) 21:523-528

Subject ID:__ __ __ -__ __ __
Visit Date: __ __/__ __/__ __ __ __
MM/DD/YYYY

Pelvic Floor Distress Inventory – Short Form 20

Instructions:
Please answer the questions by putting an X in the appropriate box. If you are unsure about how to answer a question, give the best answer you can. While answering these questions, please consider your symptoms **over the last 3 months.** CHECK ONE BOX PER QUESTION. Thank you for your help.*

1. Do you usually experience *pressure* in the lower abdomen? ☐0 No ☐ Yes
   If yes, how much does this bother you?
   ☐1 Not at all ☐2 Sometimes ☐3 Moderately ☐4 Quite a bit

◊ ◊ ◊ ◊ ◊ ◊

2. Do you usually experience *heaviness* or *dullness* in the pelvic area? ☐0 No ☐ Yes
   If yes, how much does this bother you?
   ☐1 Not at all ☐2 Sometimes ☐3 Moderately ☐4 Quite a bit

◊ ◊ ◊ ◊ ◊ ◊

3. Do you usually have a bulge or something falling out that you can see or feel in the vaginal area? ☐0 No ☐ Yes
   If yes, how much does this bother you?
   ☐1 Not at all ☐2 Sometimes ☐3 Moderately ☐4 Quite a bit

◊ ◊ ◊ ◊ ◊ ◊

4. Do you usually have to push on the vagina or around the rectum to have a complete bowel movement? ☐0 No ☐ Yes
   If yes, how much does this bother you?
   ☐1 Not at all ☐2 Sometimes ☐3 Moderately ☐4 Quite a bit

◊ ◊ ◊ ◊ ◊ ◊

5. Do you usually experience a feeling of incomplete bladder emptying? ☐0 No ☐ Yes
   If yes, how much does this bother you?
   ☐1 Not at all ☐2 Sometimes ☐3 Moderately ☐4 Quite a bit

◊ ◊ ◊ ◊ ◊ ◊

6. Do you ever have to push up on a budge in the vaginal area with your fingers to start or complete urination? ☐0 No ☐ Yes
   If yes, how much does this bother you?
   ☐1 Not at all ☐2 Sometimes ☐3 Moderately ☐4 Quite a bit

Subject ID:__ __ __ -__ __ __
Visit Date: __ __/__ __/__ __ __ __
MM/DD/YYYY

7. Do you feel you need to strain too hard to have a bowel movement? ☐0 No ☐ Yes
   If yes, how much does this bother you?
   ☐1 Not at all ☐2 Sometimes ☐3 Moderately ☐4 Quite a bit

◊ ◊ ◊ ◊ ◊ ◊

8. Do you feel you have not completely emptied your bowels at the end of a bowel movement? ☐0 No ☐ Yes
   If yes, how much does this bother you?
   ☐1 Not at all ☐2 Sometimes ☐3 Moderately ☐4 Quite a bit

◊ ◊ ◊ ◊ ◊ ◊

9. Do you usually lose stool beyond your control if your stool is well formed? ☐0 No ☐ Yes
   If yes, how much does this bother you?
   ☐1 Not at all ☐2 Sometimes ☐3 Moderately ☐4 Quite a bit

◊ ◊ ◊ ◊ ◊ ◊

10. Do you usually loose stool beyond your control if your stool is loose or liquid? ☐0 No ☐ Yes
    If yes, how much does this bother you?
    ☐1 Not at all ☐2 Sometimes ☐3 Moderately ☐4 Quite a bit

◊ ◊ ◊ ◊ ◊ ◊

11. Do you usually lose gas from the rectum beyond your control? ☐0 No ☐ Yes
    If yes, how much does this bother you?
    ☐1 Not at all ☐2 Sometimes ☐3 Moderately ☐4 Quite a bit

◊ ◊ ◊ ◊ ◊ ◊

12. Do you usually have pain when you pass your stool? ☐0 No ☐ Yes
    If yes, how much does this bother you?
    ☐1 Not at all ☐2 Sometimes ☐3 Moderately ☐4 Quite a bit

◊ ◊ ◊ ◊ ◊ ◊

13. Do you experience a strong sense of urgency and have to rush to the bathroom to have a bowel movement? ☐0 No ☐ Yes
    If yes, how much does this bother you?
    ☐1 Not at all ☐2 Sometimes ☐3 Moderately ☐4 Quite a bit

◊ ◊ ◊ ◊ ◊ ◊

Subject ID:__ __ __ -__ __ __
Visit Date: __/__/__ __ __ __
MM/DD/YYYY

14. Does a part of your bowel ever pass through the rectum and bulge outside during or after a bowel movement? ☐0 No ☐ Yes

If yes, how much does this bother you?

☐1 Not at all ☐2 Sometimes ☐3 Moderately ☐4 Quite a bit

◊ ◊ ◊ ◊ ◊ ◊

15. Do you usually experience frequent urination? ☐0 No ☐ Yes

If yes, how much does this bother you?

☐1 Not at all ☐2 Sometimes ☐3 Moderately ☐4 Quite a bit

◊ ◊ ◊ ◊ ◊ ◊

16. Do you usually experience urine leakage associated with a feeling of urgency, that is a strong sensation of needing to go to the bathroom? ☐0 No ☐ Yes

If yes, how much does this bother you?

☐1 Not at all ☐2 Sometimes ☐3 Moderately ☐4 Quite a bit

◊ ◊ ◊ ◊ ◊ ◊

17. Do you usually experience urine leakage related to coughing, sneezing, or laughing? ☐0 No ☐ Yes

If yes, how much does this bother you?

☐1 Not at all ☐2 Sometimes ☐3 Moderately ☐4 Quite a bit

◊ ◊ ◊ ◊ ◊ ◊

18. Do you usually experience small amounts of urine leakage (that is drops)? ☐0 No ☐ Yes

If yes, how much does this bother you?

☐1 Not at all ☐2 Sometimes ☐3 Moderately ☐4 Quite a bit

◊ ◊ ◊ ◊ ◊ ◊

19. Do you usually experience difficulty emptying your bladder? ☐0 No ☐ Yes

If yes, how much does this bother you?

☐1 Not at all ☐2 Sometimes ☐3 Moderately ☐4 Quite a bit

◊ ◊ ◊ ◊ ◊ ◊

20. Do you usually experience *pain* or *discomfort* in the lower abdomen or genital region? ☐0 No ☐ Yes

If yes, how much does this bother you?

☐1 Not at all ☐2 Sometimes ☐3 Moderately ☐4 Quite a bit

Subject ID: __ __ __ - __ __ __

Visit Date: __ __/ __ __/ __ __ __ __
MM/DD/YYYY

Pelvic Floor Impact Questionnaire – short form 7

Instructions: Some women find that bladder, bowel or vaginal symptoms affect their activities, relationships, and feelings. For each question, place an **X** in the response that best describes how much your activities, relationships, and feelings have been affected by your bladder, bowel, or vaginal symptoms or conditions **over the last 3 months**. Please be sure to mark an answer in **all three columns** for each question. Thank you for your cooperation.*

How do symptoms or conditions related to the following →→→→ usually affect your… ↓	**Bladder or urine**	**Bowel or rectum**	**Vagina or Pelvis**
1. ability to do household chores (cooking, housecleaning, laundry)?	☐0 Not at all ☐1 Somewhat ☐2 Moderately ☐3 Quite a bit	☐0 Not at all ☐1 Somewhat ☐2 Moderately ☐3 Quite a bit	☐0 Not at all ☐1 Somewhat ☐2 Moderately ☐3 Quite a bit
2. ability to do physical activities such as walking, swimming, or other exercise?	☐0 Not at all ☐1 Somewhat ☐2 Moderately ☐3 Quite a bit	☐0 Not at all ☐1 Somewhat ☐2 Moderately ☐3 Quite a bit	☐0 Not at all ☐1 Somewhat ☐2 Moderately ☐3 Quite a bit
3. entertainment activities such as going to a movie or concert?	☐0 Not at all ☐1 Somewhat ☐2 Moderately ☐3 Quite a bit	☐0 Not at all ☐1 Somewhat ☐2 Moderately ☐3 Quite a bit	☐0 Not at all ☐1 Somewhat ☐2 Moderately ☐3 Quite a bit
4. ability to travel by car or bus for a distance greater than 30 minutes away from home?	☐0 Not at all ☐1 Somewhat ☐2 Moderately ☐3 Quite a bit	☐0 Not at all ☐1 Somewhat ☐2 Moderately ☐3 Quite a bit	☐0 Not at all ☐1 Somewhat ☐2 Moderately ☐3 Quite a bit
5. participating in social activities outside your home?	☐0 Not at all ☐1 Somewhat ☐2 Moderately ☐3 Quite a bit	☐0 Not at all ☐1 Somewhat ☐2 Moderately ☐3 Quite a bit	☐0 Not at all ☐1 Somewhat ☐2 Moderately ☐3 Quite a bit
6. emotional health (nervousness, depression, etc.)?	☐0 Not at all ☐1 Somewhat ☐2 Moderately ☐3 Quite a bit	☐0 Not at all ☐1 Somewhat ☐2 Moderately ☐3 Quite a bit	☐0 Not at all ☐1 Somewhat ☐2 Moderately ☐3 Quite a bit
7. feeling frustrated?	☐0 Not at all ☐1 Somewhat ☐2 Moderately ☐3 Quite a bit	☐0 Not at all ☐1 Somewhat ☐2 Moderately ☐3 Quite a bit	☐0 Not at all ☐1 Somewhat ☐2 Moderately ☐3 Quite a bit

1 of 1

Subject ID:___ ___ ___ - ___ ___ ___

Visit Date: __ __ / __ __ / __ __ __ __
MM/DD/YYYY

Pelvic Organ Prolapse / Urinary Incontinence Sexual Function Questionnaire (PISQ-12)

Instructions: The following are a list of questions about you and your partner's sex life. All information is strictly confidential. Your confidential answers will be used only to help doctors understand what is important to patients about their sex lives. Please check the box that best answers the question for you. While answering the questions, consider your sexuality over the last 6 months. CHECK ONE BOX PER QUESTION. Thank you for your help.*

☐ I am not sexually active or I am not comfortable answering these questions (do not answer the questions below).

1. How frequently do you feel sexual desire? This feeling may include wanting to have sex, planning to have sex, feeling frustrated due to lack of sex, etc.
   ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never
2. Do you climax (have an orgasm) when having sexual intercourse with your partner?
   ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never
3. Do you feel sexually excited (turned on) when having sexual activity with your partner?
   ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never
4. How satisfied are you with the variety of sexual activities in your current sex life?
   ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never
5. Do you feel pain during sexual intercourse?
   ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never
6. Are you incontinent of urine (leak urine) with sexual activity?
   ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never
7. Does fear of incontinence (either stool or urine) restrict your sexual activity?
   ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never
8. Do you avoid sexual intercourse because of bulging in the vagina (either bladder, rectum, or vagina falling out)?
   ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never
9. When you have sex with your partner, do you have negative emotional reactions such as fear, disgust, shame or guilt?
   ☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never

Subject ID:__ __ __ - __ __ __

Visit Date: __ __/__ __/__ __ __ __
MM/DD/YYYY

Pelvic Organ Prolapse / Urinary Incontinence Sexual Function Questionnaire (PISQ-12)

10. Does your partner have a problem with erections that affects your sexual activity?

☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never

11. Does your partner have a problem with premature ejaculation that affects your sexual activity?

☐ Always ☐ Usually ☐ Sometimes ☐ Seldom ☐ Never

12. Compared to orgasms you have had in the past, how intense are the orgasms you have had since your last study visit?

☐ Much less intense ☐ Less intense ☐ Same intensity ☐ More intense ☐ Much more intense

2 of 2

[redacted]

Date: _____/_____/_____

Name: _____

Surgical Satisfaction Questionnaire
SSQ-8

Instructions: Following are a list of questions about your satisfaction with your surgery. All information is strictly confidential. Your confidential answers will be used only to help doctors understand and improve what is important to patients before, during and after surgery. Please check the box that best answers the question for you. Thank you for your help.

1. How satisfied are you with how your pain was controlled in the hospital after surgery?
☐ Very Satisfied ☐ Satisfied ☐ Neutral ☐ Unsatisfied ☐ Very unsatisfied

2. How satisfied are you with how your pain was controlled when you returned home after surgery?
☐ Very Satisfied ☐ Satisfied ☐ Neutral ☐ Unsatisfied ☐ Very unsatisfied

3. How satisfied are you with the amount of time it took for you to return to your daily activities, for example housework or social activities outside the home?
☐ Very Satisfied ☐ Satisfied ☐ Neutral ☐ Unsatisfied ☐ Very unsatisfied

4. How satisfied are you with the amount of time it took for you to return to work?
☐ Very Satisfied ☐ Satisfied ☐ Neutral ☐ Unsatisfied ☐ Very unsatisfied ☐ N/A

5. How satisfied are you with the amount of time it took for you to return to your normal exercise routine?
☐ Very Satisfied ☐ Satisfied ☐ Neutral ☐ Unsatisfied ☐ Very unsatisfied ☐ N/A

6. How satisfied are you with the results for your surgery?
☐ Very Satisfied ☐ Satisfied ☐ Neutral ☐ Unsatisfied ☐ Very unsatisfied

7. Looking back, if you "had to do it all over again" would you have the surgery again?
☐ Yes ☐ Maybe (probably yes) ☐ Unsure ☐ Don't think so ☐ Never

8. Would you recommend this surgery to someone else?
☐ Yes ☐ Maybe (probably yes) ☐ Unsure ☐ Don't think so ☐ Never

NOTES: Research Nurses Notes Originated 06/06

[redacted]

Subject ID#: _____Date:_____ Visit: (Circle) Pre-Op 1 2 3 4 5

Indicate pain on the line below, with one vertical mark
Do not write a number

Pelvic/Bladder Pain with **Daily** Activity

No Pain	Worst Pain
_____	

Pelvic/Bladder Pain with **Sexual** Activity

No Pain	Worst Pain
_____	

Comments:

To obtain "final" score use a 10-cm measurement tool/ruler, clinician can note precise VAS score to the tenths decimal place (e.g. 8.2 cm, 3.1 cm).

Final VAS score: _____ (Daily Activity); _____ (Sexual Activity)

VAS Entered into Database by/Date: _____ PI Review/Date: _____